

EUROPEAN E-CONGRESS OF RHEUMATOLOGY 2020

From 3 June

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EUROPEAN
E-CONGRESS OF
RHEUMATOLOGY
2020 | FROM 3 JUNE

Online Press Conference

During the European E-Congress of Rheumatology 2020 (EULAR 2020)

Date: Wednesday, June 3rd, 2020, 2:30 to 3:30 pm CEST

Topics and Speakers:

EULAR launches Virtual Research Centre: Improving the lives of people with rheumatic and musculoskeletal diseases through research

Professor Iain McInnes

EULAR President, Director of Institute of Infection, Immunity and Inflammation, University of Glasgow, Scotland/UK

Curriculum vitae: <https://orcid.org/0000-0002-6462-4280>

The EULAR COVID-19 Database: First results of patients with RMD and COVID-19

Dr. Pedro Machado

EULAR lead for the COVID-19 register, Chair of the EULAR Standing Committee of Epidemiology and Health Services Research, University College London (UCL), London, UK

Curriculum vitae: <https://orcid.org/0000-0002-8411-7972>

Thrombosis risk particularly high for people suffering from rheumatism with high inflammatory values – Reduced venous thrombosis with TNF inhibitors

Professor John Isaacs

EULAR Scientific Committee Chair, Director of Therapeutics North East, Newcastle University and Director of Research/Associate Medical Director, Newcastle upon Tyne Hospitals, UK

EULAR advocates the Deployment of other Health Care Professionals – New Study confirms their effectiveness

Dr. Kirsten Hoepfer

Hannover Medical School, Department of Rheumatology and Immunology (Medizinische Hochschule Hannover, Klinik für Rheumatologie und Immunologie)

Curriculum vitae: <https://rheumazentrum-hannover.de/>

Chair: Robert B M Landewé, Academic Medical Center/University of Amsterdam, Amsterdam/The Netherlands

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Registration: <https://attendee.gotowebinar.com/register/2294219378983570700>

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EULAR
03.06.2020
Kilchberg,
Switzerland

EUROPEAN CONGRESS OF RHEUMATOLOGY EULAR 2020, 3 – 6.6.2020 (ORIGINALLY PLANNED IN FRANKFURT/MAIN, NOW CONVERTED INTO E-CONGRESS)

The European League against rheumatism, EULAR, launches Virtual Research Centre Improving the lives of people with rheumatic and musculoskeletal diseases through research

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Kilchberg/Switzerland: Chronic and often painful rheumatic and musculoskeletal diseases disable millions of people in the EU and worldwide [1]. The causes of more than 200 of these conditions are still unknown, and there are no cures. Research and innovation are crucial to improve the understanding of the causes and characteristics of this disease group so that we can develop better prevention strategies and treatments. With this new Virtual Research Centre, the European League Against Rheumatism (EULAR) aims to provide a virtual hub to help accelerate research into rheumatic and musculoskeletal diseases across Europe and worldwide by bringing together and mobilizing a multidisciplinary research community interested in pursuing research into rheumatic and musculoskeletal diseases.

Much research is needed, including better ways to prevent these conditions, identify risk factors, and diagnose these diseases earlier. Such improvements will also help to alleviate the effects of other chronic diseases that often concur with rheumatic and musculoskeletal diseases, such as heart disease, diabetes, cancer, Alzheimer's disease, and depression.

"There are many barriers that make research into rheumatic and musculoskeletal diseases across Europe difficult," says EULAR President Professor Dr. Iain B. McInnes from Glasgow, Scotland, UK. "Reducing the burden of rheumatic and musculoskeletal diseases on individuals and societies requires comprehensive and coordinated actions at EU, national and regional level, as well as in different policy areas such as public health, health care and employment and social affairs. Under the EULAR Virtual Research Centre, we will develop initiatives that aim to bring researchers, institutions, and organizations together to start a more coordinated dialogue," explains McInnes.

Other research challenges include the limited funding that minimises what researchers can accomplish. Scientific institutions that are willing to collaborate often depend on short-term project funding which narrows the research projects and questions scientists can take on. To help address these barriers, the new EULAR Virtual Research Centre facilitates collaborative basic, clinical, and translational research to improve the lives of people with rheumatic and musculoskeletal diseases. The centre does this by providing a research roadmap that highlights unmet needs as well as research resources, infrastructure, services, and training to enable high-quality, interdisciplinary rheumatic and musculoskeletal disease research. Service examples include:

- The **EULAR Consultation Service** will provide expert advice to investigators with the goal of improving the quality of their research protocols. Researchers and health professionals can receive help with formulating research questions, methodology, and data analysis.
- The **EULAR Shared Technology Service** will help researchers to get access to the latest technology to perform innovative and high-quality research on rheumatic and

musculoskeletal diseases. The idea is to improve the quality of research and remove access barriers to innovative technology-driven research methods and equipment that researchers in low-resource settings may face.

- The centre will also offer **team science support** efforts by bringing together scientists, clinicians, health professionals, patient advocacy organisations, and other community members to solve interdisciplinary, system-wide scientific and operational problems in rheumatic and musculoskeletal disease research that no one team can overcome alone.
- Through the **EULAR School**, the Virtual Research Centre will further provide training opportunities for a highly qualified, diverse rheumatic and musculoskeletal disease workforce from researchers, clinicians and other health professionals to patient researchers. Topics will include research methods, digital health, and data science with a focus on research into rheumatic and musculoskeletal diseases.

To advance its mission, the centre also develops broad coalitions and partnerships at the local, national, and international level to integrate existing resources, support research that addresses the needs of people with rheumatic and musculoskeletal diseases, and foster innovation in the field. “Europe already has a number of excellent research networks and virtual research initiatives focused on other diseases or health topics. We look forward to forging partnerships with societies or organisations to integrate research efforts where possible across Europe and to leverage existing resources,” says McInnes.

Visit the centre’s webpage at www.eular.org.

Additional Resources:

- Factsheet on rheumatic and musculoskeletal diseases in Europe
EULAR RheumaMap

About EULAR

The European League Against Rheumatism (EULAR) is the European umbrella organisation representing scientific societies, health professional associations and organisations for people with RMDs. EULAR aims to reduce the burden of RMDs on individuals and society and to improve the treatment, prevention and rehabilitation of RMDs. To this end, EULAR fosters excellence in education and research in the field of rheumatology. It promotes the translation of research advances into daily care and fights for the recognition of the needs of people with RMDs by the EU institutions through advocacy action.

References:

[1] van der Heijde D, Daikh DI, Betteridge N, et al. Common language description of the term rheumatic and musculoskeletal diseases (RMDs) for use in communication with the lay public, healthcare providers and other stakeholders endorsed by the European League Against Rheumatism (EULAR) and the American College of Rheumatology (ACR) *Ann Rheum Dis* 2018;77:829–832.

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Study on COVID-19 in the Context of Rheumatic and Musculoskeletal Diseases Provides Reassurance to Patients on Immunosuppressive Medications

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Kilchberg/Switzerland: Different groups of drugs are used for the treatment of rheumatic conditions. They are intended to suppress the rogue immune system which attacks its own body. It is unclear to date whether the use of immunosuppressants increases the risk of a severe course in case of an infection with the novel coronavirus SARS-CoV-2. A current study published in the run-up to the European Congress of Rheumatology of the EULAR (European League Against Rheumatism) analysed, for the first time, 600 COVID-19 cases in rheumatic disease patients from 40 countries and investigated the impact of the choice of rheumatic disease therapy on potential hospitalisation and the course of COVID-19. The results of the study will be presented in today's online press conference in the context of the EULAR Congress.

Data on the course of COVID-19 in patients with rheumatic conditions are still rare and limited to small numbers of cases. Patients with rheumatic diseases are concerned about the extent to which their condition increases the risk of a severe course and the impact of the intake of their immunosuppressants on this. "There is considerable uncertainty about the drug management in the context of rheumatic conditions," EULAR President Professor Dr Iain B. McInnes from Glasgow, Scotland, United Kingdom explains.

Scientists have now addressed the question to what extent the different groups of drugs¹ increase the probability of hospitalisation in rheumatic disease patients with COVID-19. For this purpose, they analysed a series of cases involving persons with rheumatic conditions and COVID-19 from the combined EULAR and Global Rheumatology Alliance COVID-19 registries, dating from between 24 March 2020 and 20 April 2020. The study included a total of 600 cases from 40 countries.

The researchers analysed the patients' age, sex, whether they smoked or not, the rheumatic disease diagnosis, comorbidities and medication against rheumatic conditions taken immediately prior to the infection. The result: The intake of conventional disease-modifying antirheumatic drugs (csDMARDs) – such as anti-malarial drugs or methotrexate – alone or in combination with biologics (e.g. TNF-alpha inhibitors), or the intake of nonsteroidal anti-inflammatory drugs (NSAIDs) was not associated with hospitalisation. The intake of TNF-alpha inhibitors was associated with a reduced probability of hospitalisation, while no association with the intake of anti-malarial drugs was observed.

Treatment with more than 10 mg prednisone per day – corresponding to a moderate to high dose – was associated with a higher probability of hospitalisation. Prednisone is a glucocorticoid frequently used in rheumatology as a fast-acting anti-inflammatory drug.

Less than half of the patients required hospitalisation (277; 46 percent), while 55 fatalities (9 percent) occurred. This should not be interpreted as the true rate of hospitalisation and death among patients with rheumatic disease infected with SARS-CoV-2. Due to the mechanism by which case information is collected severe cases are more likely to be reported to the database (i.e. mild or asymptomatic cases are less likely to be reported) therefore artificially increasing the rate of hospitalisation/death in the group of reported patients.

"The study shows that most patients with rheumatological conditions recover from COVID-19 – independent of the medication they receive," says Professor Dr John Isaacs from The University of Newcastle, United Kingdom, Scientific Chair of the EULAR Scientific Committee. "It is necessary, however, to gather more knowledge about the course of an infection with the novel coronavirus in patients with inflammatory rheumatic conditions."

Within the space of only a few weeks, rheumatologists from all over the world teamed up in order to establish an international COVID-19 registry (www.rheum-covid.org), an effort supported by EULAR that created a mirroring COVID-19 registry (www.eular.org/eular_covid19_database.cfm). "There is an urgent need to understand the outcome of patients who have been infected with SARS-CoV-2 while at the same time receiving steroids, synthetic or biological disease-modifying anti-rheumatic drugs and nonsteroidal anti-inflammatory drugs," Dr Pedro Machado, Chair of the EULAR Standing Committee on Epidemiology and Health Services Research and co-senior author of the study, points out. "This will support rheumatologists and other health care professionals, such as specialist nurses, in advising their patients and improving their care."

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¹ Groups of drugs used in rheumatic disease therapy

In case of autoimmune diseases like rheumatoid arthritis or systemic lupus erythematosus, the immune system turns against its own body and triggers inflammations in a number of places. Treatments to suppress inflammation (immunosuppressants) and the long-term progression of the disease are required. In clinical parlance, Disease-modifying anti-rheumatic drugs (DMARDs) act by altering the underlying disease rather than treating symptoms. They're not painkillers, but they'll reduce pain, swelling and stiffness over a period of weeks or months by slowing down the disease and its effects on the joints. There are two types: conventional DMARDs and biological therapies. Biological therapies (also known as biologics) are newer drugs that have been developed in recent years. They target individual molecules, such as the tumour necrosis factor alpha (TNF-alpha), and tend to work more quickly than conventional DMARDs. In addition to these therapies, drugs containing cortisone such as glucocorticoids, which can effectively and quickly suppress the inflammatory response, are used for the treatment of rheumatic conditions. Another group of drugs used to treat rheumatic conditions are nonsteroidal anti-inflammatory drugs (NSAIDs), which alleviate pain and stiffness in the joints and improve mobility.

Further information:

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Thrombosis Risk particularly high for People suffering from Rheumatic and Musculoskeletal Disease Activity Reduced venous thrombosis with TNF inhibitors

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Kilchberg/Switzerland: People suffering from rheumatoid arthritis with increased disease activity are more often affected by thrombosis. A current Swedish study came to the result that among patients with high disease activity, one in one hundred will develop venous thromboembolism within one year, a more than twofold increase compared to patients in remission (1). Data of the German RABBIT¹ register (2) published by the European League against Rheumatism (EULAR) show that this increased risk of thrombosis can be reduced by treatment with biological disease-modifying antirheumatic drugs (bDMARD). This is important information, especially at this time during the COVID-19 pandemic, since thrombosis and pulmonary embolism also play a major role in COVID-19 infection. Vigilance for thrombosis during the treatment of people with arthritis is particularly recommended. Moreover, maintaining therapies to keep disease activity under control is vital.

Thrombosis is a significant medical problem. In the case of venous thromboembolism (VTE), clotting occurs inside a blood vessel and can affect the blood flow. Quick diagnosis and treatment are important as untreated deep vein thrombosis (DVT) in the leg can lead to potentially life-threatening pulmonary embolism: Parts of the thrombus tear off and enter a pulmonary vessel through the blood stream. In up to 30 percent of cases, patients die within 30 days after diagnosis from deep vein thrombosis in the leg or pulmonary embolism (3).

Due to chronic inflammation in patients suffering from rheumatoid arthritis, the risk of dangerous deep vein and pulmonary thrombosis is two to three times as high (3). "In the case of autoimmune diseases such as rheumatoid arthritis (RA), the immune system turns against the body and causes inflammation in a number of places. Inflammation may have a disruptive effect on coagulation," explains EULAR President Professor Dr. med. Iain B. McInnes from The University of Glasgow, UK. In people who are suffering from rheumatoid arthritis, the risk of thrombosis must always be taken into account.

The factors promoting thrombosis in patients suffering from rheumatoid arthritis and the medication that potentially reduces the risk have now been examined in two current studies.

One in one hundred patients with RA increased disease activity will suffer from thrombosis

A Swedish cohort study tried to find an answer to the question of whether the degree of disease activity has an impact on the thrombosis risk (1). The team around Viktor Molander, PhD student at the Karolinska Institutet in Stockholm analysed the data of 46,311 patients suffering from RA taken from the Swedish Rheumatology Quality Register (SRQ) over a period of 12 years. For the

measurement of disease activity the "Disease Activity Score 28" (DAS28) was used. The DAS28 assesses the disease activity of rheumatoid arthritis based on the assessment of 28 defined joints.

The study indicates a close connection between the clinical disease activity of RA measured by DAS28 and the risk of VTE: Molander came to the result that "among patients with high disease activity, one in one hundred is going to develop VTE within the following year, a more than twofold increase compared to patients in remission."

"Having regular check ups by a rheumatologist can be inconvenient. However, it is an important measure to monitor the development of the condition and whether treatment has to be adjusted accordingly," explains EULAR Scientific Chair Professor Dr. John Isaacs from The University of Newcastle, UK.

Biologics can reduce the risk of thrombosis

The risk of thrombosis is also influenced by the medication used in rheumatoid arthritis cases. Conventional synthetic disease-modifying anti-rheumatic drugs (csDMARD) such as Methotrexate, Sulfasalazine and Leflunomide are part of the basic treatment of RA. A next step are biologics (bDMARD), which also include tumour necrosis factor (TNF) inhibitors like Adalimumab, Certolizumab Pegol, Etanercept, Golimumab and Infliximab.

The question of whether the risk of thrombosis is reduced by application of bDMARDs such as TNF inhibitors in comparison to csDMARDs was addressed in a scientific study including the lead author Dr. rer. nat. Martin Schäfer from the programme area of Epidemiology at the German Rheumatism Research Center, Berlin, Germany. For this purpose, the team has analysed the data of more than 11,000 RA patients in the German RABBIT¹ register, who were treated either with another csDMARD after at least one csDMARD failure, or whose treatment was switched to bDMARD.

The result: "By treatment with TNF inhibitors, the risk of major VTE events is reduced by almost half in comparison to csDMARDs," explains Schäfer. According to the RABBIT data, an increase in inflammatory activity was also associated with a significant increase in the risk of VTE: The risk was approximately twice as high as a CRP value of at least 5 mg/l. "For patients with an increased risk of thrombosis, alternative treatment with TNF inhibitors, and possibly other biologic drugs, should be considered instead of standard csDMARD treatment," concludes PD Dr. med. Anja Strangfeld, study manager at RABBIT register in Berlin and co-author of the study. "Reducing the inflammatory activity is also an important factor to reduce the risk of VTE."

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- 2.) Schäfer M, Schneider M, Graessler A et al. TNF inhibitors are associated with a reduced risk of venous thromboembolism compared to csDMARDs in RA patients DOI: 10.1136/annrheumdis-2020-eular.1505
- 3.) Chung W, Peng C, Lin C et al.: Rheumatoid arthritis increases the risk of deep vein thrombosis and pulmonary thromboembolism: a nationwide cohort study. *Annals of the Rheumatic Diseases* 2014;73:1774–1780.

¹ RABBIT stands for "**R**heumatoide **A**rthritis: **B**eobachtung der **B**iologika**T**herapie" and is a registry of the German Rheumatism Research Center Berlin (DRFZ) for long-term study of patients suffering from rheumatoid arthritis. RABBIT was initiated in 2001 and is a nationwide programme. Its main target is the analysis of the efficiency and safety of treatment measures against RA in clinical practice.

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European League Against Rheumatism advocates the Deployment of Other Health Care Professionals – New Study confirms their Effectiveness Insufficient health care for people with rheumatic diseases in Germany

Kilchberg/Switzerland – Inflammatory-rheumatic disorders are a widespread ailment, affecting at least 1.5 million people in Germany alone. Because there is a shortage of rheumatologists, however, only half of the patients in this country are adequately treated (1,2). The use of other health care professionals, as is the case in Denmark and the UK, could help to improve the situation. A study in Germany has shown for the first time that the care of patients with inflammatory-rheumatic diseases by ‘rheumatological assistants’ (RFA*) is just as effective as treatment by specialist rheumatologists. To reduce waiting times and prevent damage to health, the European League Against Rheumatism (EULAR) strongly recommends the use of RFAs in Germany, which will be announced in today’s press conference held for its annual congress.

Around two percent of the adult population in Germany is affected by chronic inflammatory rheumatic diseases, such as rheumatoid arthritis (RA), axial spondyloarthritis (axSpA) or psoriatic arthritis (PsA) (1). “These patients have a considerable medical condition,” explains Dr. Kirsten Hoyer from the Clinic for Rheumatology and Immunology at the Hanover Medical School in Germany.

Missed opportunities for treating patients due to long waiting times

Severe pain, extreme fatigue, lack of strength, stiffness and physical deformity can have a significant impact on activities, education and career, partnership and family and can lead to occupational disability. Early diagnosis and therapy are essential to prevent as far as possible such serious consequences of damage to the joints. “But the existing medical resources do not suffice to provide early, patient-centred and guideline-based care. The waiting times are far too long,” states Hoyer. “This is despite the fact that new drugs could almost completely force the disease back into so-called remission for the majority of patients - provided that treatment is administered in good time.”

The deployment of RFAs could improve the situation, as is already well-established in some Northern European countries. RFAs are members of related medical professions such as paramedic, nurse, student nurse or road traffic/motor traffic accidents, who have acquired additional theoretical and practical knowledge about the care of patients suffering from rheumatic and musculoskeletal diseases (RMDs) (3). Such a delegation of medical care in rheumatology is recommended worldwide (4-8, 9). “The legal framework for this also exists in Germany,” says Hoyer (10). “In addition, the curriculum for the RFA degree exists since 2006, which is currently available to the German Medical Association for certification in an extended form (3).

In order to examine whether and how RFAs can also be used in the German health care system, a prospective, randomised, controlled and multi-centre study was conducted, which was completed in December 2019. “A total of 236 patients from eight German centres participated in

the study, where a blood test had confirmed the diagnosis of rheumatoid arthritis,” explains the author of the study Hoepfer.

Study Involvement of RFAs produces the same treatment results

On average, the patients were 58 years of age, over 70 percent were female and suffered from rheumatic complaints for a period of 130 (ranging from 12 to 144) months on average. While one study group was exclusively treated by rheumatologists during the twelve-month study period, the other study group RFAs temporarily took over the care at three fixed intervals with only brief contact to the physicians. The patients' condition was measured using the standard assessment form DAS28 (Disease Activity Score at 28 joints), which assesses the activity of the disease on an ascending scale from 2.0 to 10.0. Values between 3.2 and 5.1 are considered moderate.

Result of the study: The structured delegation of medical tasks to an RFA does not undermine the current standard of care. While the disease activity for the group co-treated by RFAs was on average DAS28 2.43, the value for the group with continuous rheumatologist consultation was on average DAS28 2.29. “This difference is not clinically or statistically significant”, concludes EULAR President Professor Dr. Iain B. McInnes from Glasgow, Scotland, UK. “For the first time it can be shown for Germany that an RFA consultation is a safe way to complement the care of patients suffering from rheumatoid arthritis”, says Professor Dr. med. John Isaacs from Newcastle, Great Britain, EULAR Scientific Programme Committee Chair.

Better care in a cost-efficient way

“Integrating a team approach comprising rheumatologists with other health professionals into the treatment of patients with inflammatory rheumatic diseases presents great opportunities,” emphasises McInnes. “RFAs can complement a physician’s workload, who in turn can use freed-up resources for more complex or new patients,” Hoepfer adds. The long waiting times for an appointment with a rheumatologist could thus be cut shorter. Hoepfer concludes, “by following the international EULAR Recommendations regarding RFAs, Germany will lead to better patient care in a cost-efficient way”.

* RFA: Rheumatologische Fachassistenz

Notes to editors:

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S P E E C H M A N U S C R I P T

The EULAR COVID-19 Database: First results of patients with RMD and COVID-19

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What is the question about?

The coronavirus disease 2019 (COVID-19) pandemic caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) virus is of particular concern for people with rheumatic and musculoskeletal diseases (RMDs) or those who are immunosuppressed. Whether having a RMD or receiving immunosuppressive treatment is associated with severe infection and subsequent poor outcomes is unknown. In general, immunosuppression and the presence of comorbidities are associated with an increased risk of serious infection in people with RMDs therefore, people with RMDs may be at higher risk for a more severe course with COVID-19, including hospitalization, complications and death. Importantly, some medications used to treat RMDs, such as hydroxy-chloroquine and interleukin-6 inhibitors, are being studied for the prevention and/or treatment of COVID-19 and its complications including cytokine-storm.

The implications of COVID-19 for people living with RMDs is poorly understood. To address this knowledge gap, a global network of rheumatologists, scientists, and patients developed a physician-reported case registry of people with RMDs diagnosed with COVID-19. We aimed: (1) to describe the demographic and clinical characteristics of the first 600 patients submitted to the combined EULAR and Global Rheumatology Alliance COVID-19 physician registry, and (2) identify factors associated with hospitalization for COVID-19 in this population.

What are the most important core statements/points?

- Taking oral steroids at a dose of 10mg or more was associated with an increased odds of hospitalization.
- Taking non-steroidal anti-inflammatories and other a medications like hydroxychloroquine, methotrexate, biologics or JAK inhibitors was not associated with an increased odds of hospitalisation.
- We found that taking TNF inhibitors reduced the odds of hospitalisation for COVID-19.
- As in the general population, people with rheumatic diseases who are older (>65 years) and/or have comorbidities (hypertension/cardiovascular disease, lung disease, diabetes, chronic renal disease/end stage renal disease) have a higher odds of COVID-19-related hospitalization.

What is new about it?

This study described the largest collection of COVID-19 cases amongst patients with RMDs, with 600 cases from 40 countries. It provides, for the first time, information about the outcome of COVID-19 in patients with RMDs and it informs about risk factors for hospitalisation. This study demonstrated that

most individuals with rheumatologic diseases or on immunosuppressive therapies recover from COVID-19, which should provide some reassurance to patients.

What significance do the findings have for patients in Germany/Europe/World? Have they already reached the clinic?

These results will inform the management of patients with RMDs in the context of SARS-CoV-2/COVID-19 and are therefore relevant to all rheumatologists and physicians/health care professionals treating patients with RMDs and COVID-19 worldwide.

Results support the guidance issued by the European League Against Rheumatism (EULAR) which suggest continuing rheumatic medications in the absence of COVID-19 infection or SARS-CoV-2 exposure.

Further discussion about findings

It is important to be aware that the data were not collected across the entire population of patients with RMDs so it is not possible to know the rate of hospitalization or death in RMD patients overall. It is likely that more severe patients were collected in the registry. Based on this data, most patients with RMDs don't seem to be at an increased risk of hospitalisation due to the medicines they take for their underlying problem. We do need to collect more data, and collect more data in different ways to confirm this finding.

In accordance with previous studies of COVID-19 in different populations, we found that patients with comorbidities such as hypertension, cardiovascular disease, and diabetes had higher odds of hospitalization. We also found that glucocorticoid use at a prednisone-equivalent dose >10 mg/day was associated with an increased odds of hospitalization, which is in agreement with prior studies showing an increased risk of infection with higher dose of glucocorticoids.

We did not find a significant association between antimalarial use and hospitalization in adjusted analyses. The use of hydroxychloroquine for the treatment of COVID-19, which was based on *in vitro* studies, has had mixed results.

We also did not detect a significant association between NSAID use and hospitalization in adjusted analyses. Although no prior data in COVID-19 patients have supported a deleterious effect of NSAIDs on clinical outcomes, early reports cautioned against the use of NSAIDs suggesting harm when used during the clinical course of COVID-19.³⁰ These observations, while anecdotal, may also relate to confounding by indication, since NSAIDs are also often sold over-the-counter and may not be documented in hospital records with the same accuracy as prescription medications, leading to a reporting bias.

We found a lower odds of hospitalization with b/tsDMARDs monotherapy in our primary multivariable analysis, which was driven largely by anti-TNF therapies. The number of cases taking other biologic drugs or Janus kinase inhibitors was small, and may have been insufficient to demonstrate other underlying effects if present. Although we caution against causal inference regarding drug effects given significant potential for residual confounding in our study, we also note that there is biological plausibility for the potential benefit of biologic medications in treating COVID-19, as evidenced by

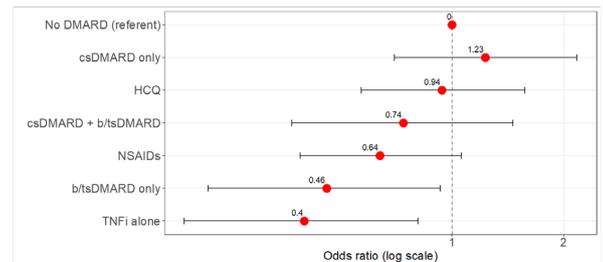
those with more severe disease having higher levels of cytokines, including IL6 and TNF. The use of IL-6 inhibitors is being investigated for COVID-19, particularly in cases complicated by aberrant inflammatory responses or 'cytokine storm'. This is based on two initial case series of fewer than 20 patients. Anti-TNFs have also been suggested as a potential therapy in COVID-19, but this has been based solely on pre-clinical data. Randomized, placebo-controlled trials are needed to clarify potential benefits or harms of biologic therapies in treating COVID-19.

Figures

Registry Demographics

- Total n = 600
- Female = 473 (71%)
- Median age 56 years (45 - 67)
- North America 57%
- Europe 36%
- Other 7%
- Rheumatic Diagnoses
 - Rheumatoid arthritis 230 (38%)
 - Systemic Lupus 85 (14%)
 - Psoriatic arthritis 74 (12%)
 - axial SpA 48 (8%)
 - Vasculitis 44 (7%)
 - Sjogren's 28 (5%)
 - inflam myopathy 20 (3%)
 - Gout 19 (3%)
 - Systemic Sclerosis 16 (3%)

Odds of Hospitalisation for COVID-19 by Medication



Gianfrancesco et al. Ann Rheum Dis 2020

csDMARD = methotrexate, leflunomide, hydroxychloroquine; NSAIDs= Non-steroidal anti-inflammatories
b/tsDMARD = biologics (including TNFi) & JAK inhibitors; TNFi = tumour necrosis factor inhibitors

Gianfrancesco et al. Ann Rheum Dis 2020

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SPEECHMANUSCRIPT

Effect of nurse-led-care on patient outcomes in rheumatoid arthritis in Germany: A multicentre randomised controlled trial

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Rationale

Chronic inflammatory rheumatic diseases are common. Approximately two per cent of the adult population in Germany suffers from rheumatoid arthritis (RA), axial spondyloarthritis (axSpA) or psoriatic arthritis.[1] Newly developed drugs could, in principle, induce remission in the majority of these patients. Yet, rheumatology faces major challenges in Germany as, due to the current shortage of rheumatologists, only half of the patients receive appropriate care.[1,2] Demographic changes will lead to higher numbers of rheumatology patients. Unless new ways of looking after them can be found, the situation can only get worse.

Patients with chronic inflammatory conditions have a high disease burden. These conditions have a great impact on their inclusion in normal activities, such as relationships and family life, training and working life. Current medical resources are insufficient to provide early, patient-centred and guideline-based care.

The practice of using rheumatology nurse practitioners (RNPs) to look after patients with inflammatory rheumatic diseases has been established for some time in several countries in northern Europe. RNPs are nurses and allied health professions, e.g. radiographers, lab technicians, who have had additional training in the theory and practice of caring for rheumatology patients. [3] Several studies in these countries have demonstrated that, measured in terms of disease activity, the care of patients by RNPs was not inferior to that provided solely by a rheumatologist. [4–9] However, due to the differences in the health care systems, these findings can not be totally applied to Germany.

The employment of RNPs currently plays no part of the rheumatology care routine in Germany, even though:

- care provision for patients with inflammatory rheumatic conditions is inadequate,
- delegation of medical tasks in rheumatology is backed up by international scientific evidence[4-8] and recommended [9],
- the legal base for such delegation has been established in Germany [10], and
- a certification course for the qualification “Rheumatology Nurse Practitioner” (Rheumatologische Fachassistenz DGRh¹/BDRh²) has been introduced in 2006. An extended course (RFAplus) is currently awaiting certification by the German Medical Association. [3]

¹ German Society for Rheumatology (Deutsche Gesellschaft für Rheumatologie, DGRh)

² Association of German Rheumatologists (Berufsverband Deutscher Rheumatologen, BDRh)

Effectiveness of RFA-led clinics – ERFASS trial

The objective of this study is to demonstrate that the international experiences of RNP-led clinics within the rheumatology care structure can be replicated in Germany. It is a prospective multicentre randomised controlled trial, carried out in eight centres in Germany between 1 January 2018 and 31 August 2018. 236 patients with seropositive rheumatoid arthritis were included in the study at initiation, change or escalation of treatment regime. The follow-up period concluded in December 2019. The treat-to-target visits after 4 to 6 weeks and two of the possible four annual visits were conducted by an RNP in the intervention group. The length of time of any subsequent rheumatologist contact was based on the patient's condition and needs. Patients in the control group were only seen by a rheumatologist.

The results demonstrate that, in terms of disease activity, delegation of medical tasks to RNPs within the rheumatology structure is not inferior to the current standard of care. This trial has provided the first scientific evidence that RNP-led clinics are a safe addition to the care of rheumatoid arthritis patients in Germany. The trial also demonstrated that the ratings for the quality of treatment, trust in the practitioner and satisfaction with the treatment given by patients in the intervention group were similar to those in the control group.

Integrating RNPs into the multi-disciplinary team caring for patients with inflammatory rheumatic diseases offer great opportunities. At the same time, structures designed to relieve the burden on rheumatologists can be created whilst providing a comparable quality standard of care. The medical resources freed up can be used for more complex or new patients and will shorten the long waiting times for a rheumatology appointment. A more efficient use of resources could lead to long-term cost savings without compromising patient care.

Germany is therefore yet another European country to follow the international recommendations of EULAR. Patient care provided by RNPs is gaining in importance, and could also be introduced elsewhere in Europe over the coming years.

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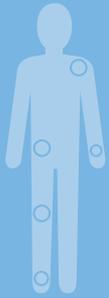
The ERFASS study is a sub project of the Rheuma-VOR trial funded by the German Innovationsfonds (Funding Code: 01NVF16029).

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RHEUMATIC AND MUSCULOSKELETAL DISEASES IN EUROPE

There are more than 200 rheumatic and musculoskeletal diseases (RMDs).¹

200+



RMDs commonly affect the joints but can affect any organ in the body.¹

They can start at any age and can develop in children.¹



Many of these diseases are chronic and worsen over time, they are typically painful and limit function.¹

They are usually caused by problems of the immune system, inflammation, infections or gradual deterioration of joints, muscles and bones.¹



Rheumatoid Arthritis RA

The most common autoimmune inflammatory form of arthritis.²

- Inflamed joint-linings erode cartilage and bone, causing joint deformities and progressive physical disability.³
- Affects approximately one in 100 persons worldwide, RA is twice as common in women as in men.²

1
persons
worldwide

100

2x
more frequent
in women

Osteoarthritis OA

The most common joint disorder, accountable for more disability in the elderly than all other diseases together.⁴

- Cartilage degrades and bone-on-bone contact upon weightbearing and joint mobilisation causes pain, inflammation, swelling and loss of motion.⁴
- By 2050, 130 million people will suffer from osteoarthritis worldwide and 40 million will be severely disabled.⁵

2050

130
million

Gout

The accumulation of urate crystals in the (joint) tissues can cause acute arthritis and may lead to kidney failure.⁶

- Symptoms include joint damage, renal stone formation and excruciating pain due to acute inflammation.⁷
- The most common cause of inflammatory arthritis in men.⁸
- Almost as many people suffer from gout as RA.⁹



Systemic Lupus Erythematosus SLE

A systemic autoimmune disease that can cause arthritis and tissue damage in multiple organs leading to serious complications.^{10,11}

- A rare disease, 24/100,000 in the global population suffer from SLE.¹²
- Affects women approximately nine times more frequently than men.¹³

9x
more frequent
in women



Juvenile Idiopathic Arthritis JIA

Includes seven subtypes of chronic arthritis in children with uncertain or unknown origin.^{14,15}

- JIA affects a range of children worldwide from 0.07 to 4 in 1,000.¹⁶
- Symptoms include joint pain, swelling, tenderness and stiffness that lasts for more than six weeks as well as damage to the eyes and lymph nodes.¹⁵

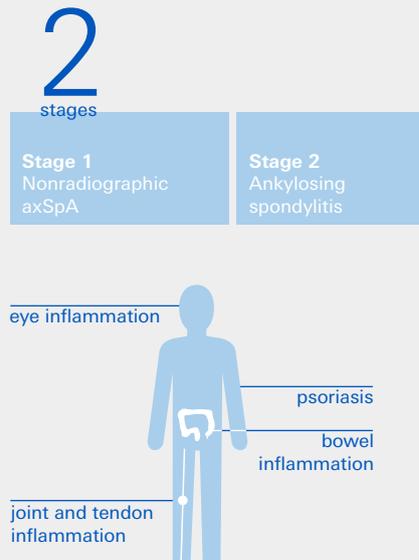
6+
weeks
duration



Axial Spondyloarthritis

A chronic inflammatory disease predominantly affecting the spine and the joints connecting the spine and pelvis, which may lead to extra bone formation, resulting in a fused spine.¹⁷

- Patients frequently suffer from inflammation in the joints and tendons, as well as psoriasis, inflammatory bowel disease and inflammation of the eye (i.e. uveitis).¹⁷
- There are two stages; nonradiographic axSpA, which shows normal joints on a radiograph, followed by the radiographic form also known as ankylosing spondylitis (AS).¹⁷
- Up to 0.9% of people worldwide suffer from AS.¹⁷

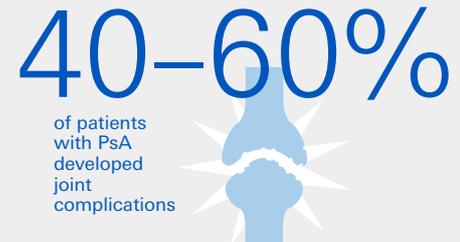


Psoriatic Arthritis

PsA

A chronic disease with inflammation of synovial tissues (joints), tendons and skin.¹⁸

- PsA-induced joint damage affects patients' ability to work and their social relationships.¹⁹
- In the past decade, 40–60% of patients with PsA have developed erosive and deforming joint complications.¹⁹



Fibromyalgia

A chronic disorder causing muscle pain, sleep disturbances, headaches, and tingling/numbness of extremities.²⁰

- While the causes are unknown, development is often associated with a physically or emotionally stressful or traumatic event.²⁰
- The presence of other rheumatic disease such as RA or SLE may increase the likelihood of developing fibromyalgia.²⁰
- Up to 2% of the population suffers from this condition.²¹

2%

Osteoporosis

OP

Skeletal disorder characterised by low bone density and structural deterioration of bone tissue, which leads to bone fragility and increased susceptibility to fracture.²²

- In the EU 22 million women and 5.5 million men are estimated to have osteoporosis.²³



Systemic Scleroderma

SS

Scleroderma leads to fibrosis of the skin and organs.²⁴

- Symptoms include thickened skin, skin discolouration, ulcers, painful and swollen joints and organ manifestations (digestive tract, lungs) due to fibrosis.^{24,25,26}
- There are an estimated 2.5 million active cases of SS worldwide.²⁷



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EUROPEAN E-CONGRESS
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From 3 June

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Fact Sheet EULAR

About EULAR

The European Congress of Rheumatology EULAR 2020 is the congress of the national European rheumatic associations. The most important congress in this field is aimed at all involved in this disease: doctors, researchers, professionals, patient organisations and industry. The event was originally planned to take place in Frankfurt am Main, Germany, from 3 to 6 June 2020. Due to the COVID-19 pandemic, the European Congress of Rheumatology EULAR 2020 will now take place as a virtual congress from 3 June 2020. The contents are available online until 1 September 2020.

The congress is organised by the *European League Against Rheumatism* ([EULAR](https://www.eular.org)). EULAR is a non-profit scientific organisation based in Zurich, Switzerland, representing scientific societies, societies of other health professionals, professional associations and organisations for people with rheumatic and musculoskeletal diseases (RMDs). The aim of EULAR is to reduce the burden of RMDs on the individual and society and to improve the treatment, prevention and rehabilitation of RMDs.

Further information: www.eular.org

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