EULAR
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Kilchberg,
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NEW EULAR CONSENSUS ON PREVENTION TRIALS IN PEOPLE AT RISK OF DEVELOPING RA

EULAR has released new points to consider for studies looking at preventing RA in people identified as at risk

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In recent years, it has become clear that rheumatoid arthritis (RA) has a preclinical phase – a period before the disease has fully developed. This understanding has allowed the identification of people who are at risk of developing RA. There are a variety of genetic and environmental factors that make developing RA more likely. As autoantibodies and symptoms develop, these at-risk people eventually progress to clinical arthritis and classifiable RA. Despite growing interest in treatments to prevent RA, there is no guidance or consensus on how to conduct trials in at-risk populations.

RA is an inflammatory autoimmune disease that causes pain, swelling and stiffness in the joints. It can also cause fatigue, and the underlying inflammation may affect other body systems. Treating RA quickly after diagnosis and as early as possible after symptom start has been shown to have a significant impact in its further development. With the discovery of the preclinical phase of the disease, the idea of treating people who are at-risk with the aim of *preventing* RA is very attractive. However, to do this requires carrying out clinical trials to assess the safety and efficacy of treatments in the 'pre-RA' phase. Some initial trials in this area have looked at very different populations – with variation in eligibility criteria, biomarkers, interventions, and outcomes. This makes it hard to interpret and compare the evidence as it accumulates.

A EULAR taskforce was set up to develop a set of points to consider for investigators in this important new area. The taskforce included scientists, rheumatologists, and patient representatives. They looked at the published evidence around risk factors and interventions.

In total, 10 points to consider have been produced. These all fall under one overarching principle, which states that all clinical trials and observational studies in people at risk of RA should include the epidemiological and demographic characteristics of the at-risk population being studied. The individual points consider who should take part in trials, and what information they should be given about their risks. They also make suggestions for some study endpoints that should be used across trials.

For trial populations, at-risk participants should be identified according to their clinical presentation. Within this, subpopulations should be identified based on specific risk factors. These risks should be assessed in a population-specific manner, and include a composite of core and emerging risk factors that are assessed at the study start – and potentially repeated throughout. Candidates for clinical trials and observational studies should be informed about their risk of developing RA as this may affect their decision to take part.

The group agreed that the development of subclinical inflammation, clinical arthritis or progression to RA should be considered as study endpoints across trials, whereas disease remission may also be appropriate in people with palindromic rheumatism or undifferentiated arthritis. Clinical trials should evaluate the ability of a specific intervention to modify risk factors as well as progression to RA.

These consensus statements provide guidance for rheumatologists, health professionals and investigators conducting clinical trials and observational studies in people at risk of RA.

Source

Mankia K, Siddle HJ, Kerschbaumer A, et al EULAR points to consider for conducting clinical trials and observational studies in individuals at risk of rheumatoid arthritis Annals of the Rheumatic Diseases Published Online First: 06 August 2021. doi: 10.1136/annrheumdis-2021-220884

About EULAR

EULAR is the European umbrella organisation representing scientific societies, health professional associations and organisations for people with rheumatic and musculoskeletal diseases (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.

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