Taskforce creates guidelines for prevention trials for people at risk of developing rheumatoid arthritis

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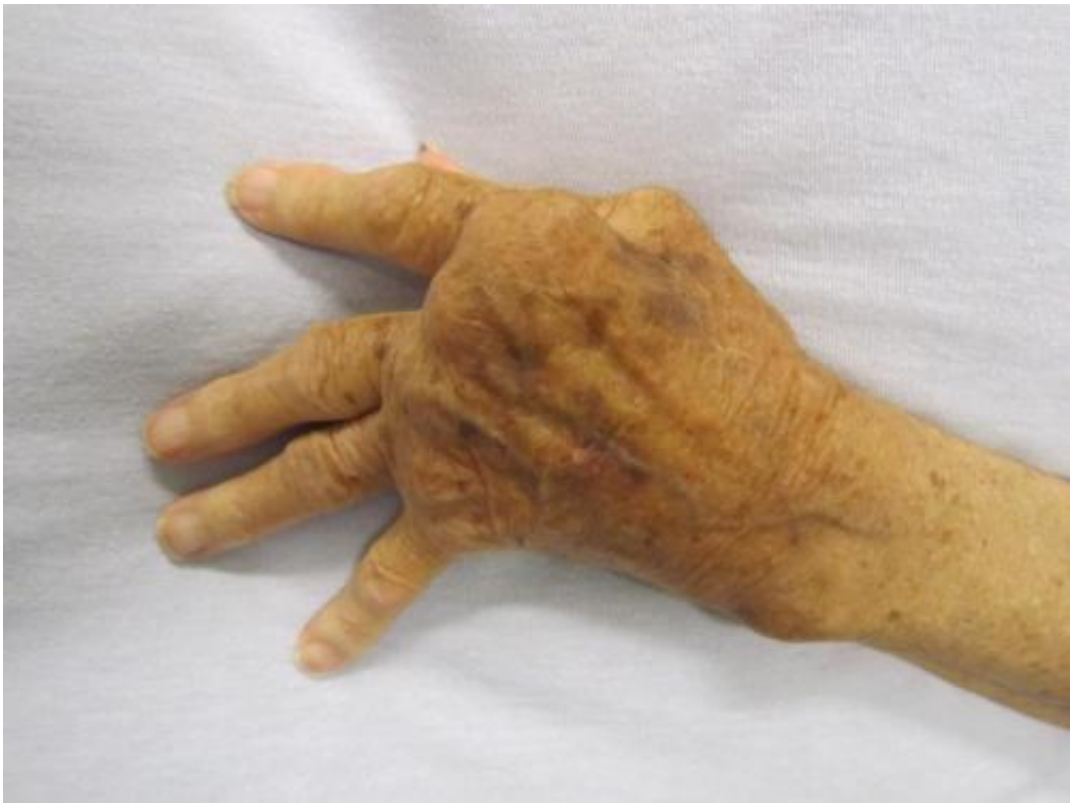

A hand affected by rheumatoid arthritis. Credit: James Heilman, MD/Wikipedia

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.

More information: Kulveer Mankia 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* (2021). DOI: 10.1136/annrheumdis-2021-220884

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