

# The use of placebo in rheumatoid arthritis clinical trials may negatively impact patients

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The results of this study, conducted in Germany, re-open the debate on whether it is ethical to conduct placebo-controlled studies where patients in the placebo-group are at a serious disadvantage compared to patients taking the new treatments. The study analysed current study designs, for new therapies such as abatacept (Orencia®), golimumab (Simponi®) or tocilizumab (Actemra®), and showed that patients in the placebo group experienced no change in medication, having to continue with their former, ineffective treatment plus placebo.

"According to the Helsinki-Declaration of the World Medical Association\*, a placebo-controlled study design is deemed to be ethically acceptable when there is no other effective treatment," said Dr. Juche, Johanniter-Hospital, Treuenbrietzen, Germany. "However, this analysis confirms that patients in the [placebo-group](#) are at a disadvantage as they are given no change in medication to reduce their active inflammatory condition or halt disease progression. Our recommendation is that future clinical trials should include an active comparator group to ensure that all [patients](#) receive effective treatments to improve their quality of life."

In the analysis, researchers used studies from the European Public Assessment Report (EPAR) of the European Medicines Agency (EMA) for abatacept, golimumab and tocilizumab as samples. The studies chosen had to be [placebo](#) controlled at the beginning and state clinical relevant outcome criteria (e.g. DAS28\*\*, ACR20\*\*\*, Health Assessment Questionnaire and joint erosion scores).

**More information:** \*The World Medical Association (WMA) is an organisation promoting the highest possible standards of medical ethics. The WMA provides ethical guidance to physicians through its Declarations, Resolutions and Statements.

\*\*DAS28 (Disease Activity Score) is an index used by physicians to measure how active an individual's RA is.

\*\*\*ACR (American College of Rheumatology) criteria measures improvement in tender or swollen joint counts.

Provided by European League Against Rheumatism

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