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Hydroxychloroquine in patients with inflammatory and erosive Osteoarthritis of the hands (OA TREAT): Study protocol for an ongoing randomized controlled trial

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Background: Osteoarthritis (OA) is a heterogeneous group of conditions with disturbed integrity of articular cartilage and changes in the underlying bone. The pathogenesis of OA is multifactorial and not just a disease of older people. Hydroxychloroquine (HCQ) is a Disease-Modifying Anti-Rheumatic Drug (DMARD) typically used for the treatment of various rheumatic and dermatologic diseases. Despite initial evidence for good efficacy of HCQ, there has been no randomized, double-blind, and placebo-controlled trial in a larger patient group.

Methods/Design: OA TREAT is an investigator-initiated, multi-center, randomized, double-blind, placebo-controlled trial. A total of 510 subjects with inflammatory and erosive hand OA, according to the classification criteria of the American College of Rheumatology (ACR) with recent X-ray, will be recruited across outpatient sites, hospitals and universities in Germany. Patients are randomized 1:1 to active treatment (HCQ 200-400 mg per day) or placebo for 52 weeks. Both groups receive standard therapy (Non-Steroidal Anti-Inflammatory Drugs [NSAID], coxibs) for OA treatment, taken steadily two weeks before enrolment and continued further afterwards. If disease activity increases, the dose of NSAID/coxibs can be increased according to the drug recommendation. The co-primary clinical end-points are the changes in Australian-Canadian OA Index (AUSCAN, German version) dimensions for pain and hand disability at week 52. The co-primary radiographic end-point is the radiographic progression from baseline to week 52. A multiple end-point test and analysis of covariance will be used to compare changes between groups. All analyses will be conducted on an intention-to-treat basis.

Discussion: The trial OA TREAT will examine the clinical and radiological efficacy and safety of HCQ as a treatment option for inflammatory and erosive OA over 12 months. OA TREAT focuses on erosive hand OA in contrast to other current studies on symptomatic hand OA, for example, HERO [Trials 14:64, 2013].

Biography

Pascal Klaus, graduated from Charité - Universitätsmedizin Berlin, Germany, in 2011. He is currently an intern and scientific associate at the Department of Rheumatology and Clinical Immunology at Charité - Universitätsmedizin Berlin (director: Prof. G.-R. Burmester). There, he is pharmacovigilance assignee for INSIDER, the division for investigator-initiated trials in rheumatology, led by J. Detert, MD.

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