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Changes in Bone Mineral Density and Incidence of Fractures during Two Years of Low Dose Glucocorticoid Treatment for Rheumatoid Arthritis: Protocol for a Systematic Review and Individual Participant Data Meta-Analysis

Andriko Palmowski¹

¹Department of Rheumatology and Clinical Immunology, Charité -University Medicine Berlin, Germany



Andriko Palmowski

Department of Rheumatology and Clinical Immunology, Charité ...

ABSTRACT

Background

Glucocorticoids (GCs) are regularly used drugs in the treatment of rheumatoid arthritis (RA), and lower bone mineral density and fractures are common adverse effects of the treatment with higher GC dosages. However, the effects of low dose (i.e., \leq 7.5mg/day) and very low dose (i.e., \leq 5mg/day) treatment over longer periods of time (i.e., \geq 24 months), as often seen in RA, have not been fully elucidated yet.

Objective

To conduct a systematic review and meta-analysis of individual patient data from long-term randomized controlled trials (RCTs) in RA, which compared low dose GCs to a control treatment, in order to investigate the effects on bone mineral density and incidence of fractures (clinical/symptomatic).

Methods

We will search the literature to identify published trials which collected data on bone mineral density and/or the incidence of fractures. This will be followed by the acquisition of individual participant data. Included RCTs will be combined to compare bone mineral density and fractures in GC and control groups. To underpin our findings, we will perform additional analyses to identify potential effect modifiers and a sensitivity analysis related to missing data.

PDF Protocol

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