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IN BRIEF

GUIDELINES

CONSORT statement extended for pilot trials

The Consolidated Standards of Reporting Trials (CONSORT) statement, which has a continuing aim to improve randomized controlled trial (RCT) quality and minimize bias, has now been extended to randomized pilot and feasibility trials. In the extension, the guidelines have been adapted to suit the different focus of pilot trials, which assess feasibility of conducting a future definitive RCT rather than effectiveness or efficacy of an intervention. Additional items in the extension include the criteria used in deciding whether to progress to a future definitive RCT, to proceed with amendments, or not to proceed; they also cover the implications in going forward and how any proposed amendments should be taken into consideration. It is hoped this proposed extension will improve the conduct and reporting of pilot trials.

ORIGINAL ARTICLE Eldridge, S. M. *et al.* CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ* http://dx.doi.org/10.1136/bmj.i5239 (2016)

UNDIFFERENTIATED ARTHRITIS

Abatacept for treating ACPA-negative UA?

A proof-of-concept prospective, open-label study has shown that abatacept has promise as a treatment for patients with anti-citrullinated protein antibody (ACPA)-negative undifferentiated arthritis (UA) and poor prognosis (power Doppler ultrasonography (PDUS) score ≥1). The primary end point was a composite of DAS44 remission (DAS44 <1.6, where DAS44 is the disease activity score incorporating 44-joint swollen joint count, Ritchie Articular Index and erythrocyte sedimentation rate), a maximum of one swollen joint for ≥3 consecutive months, and no measured radiographic progression at 6 months. Two of the 20 (10%) patients treated with abatacept monotherapy for 6 months achieved the defined primary end point, and six (30%) achieved DAS44 remission (95% CI 15–51%) by 6 months. By 12 months, 8/20 (40%) patients achieved DAS44 remission (95% CI 22–61%); the mean DAS44 was reduced from 2.66 to 1.78 and the median PDUS score reduced from 10 to 3 at this time point.

ORIGINAL ARTICLE Buch, M. H. *et al.* Abatacept reduces disease activity and ultrasound power Doppler in ACPA-negative undifferentiated arthritis: a proof-of-concept clinical and imaging study. *Rheumatology (Oxford)* http://dx.doi.org/10.1093/rheumatology/kew357 (2016)

RHEUMATOID ARTHRITIS

Bone-healing effects of denosumab in RA

Post-hoc analysis of a randomized controlled trial investigating denosumab and alendronate therapy has found that denosumab treatment reduced the size of existing bone erosions in female patients with rheumatoid arthritis (RA). The patients studied were randomly assigned to receive either one subcutaneous injection of denosumab 60 mg (n = 20) or oral alendronate 70mg weekly (n = 20). The width, depth and volume of bone erosions were significantly reduced after 6 months of denosumab treatment (P <0.01), as measured by high-resolution peripheral quantitative CT. By constrast, these measures of bone erosion were significantly increased in alendromate-treated patients after 6 months (P <0.01). Compared with baseline values, the denosumab group also showed significantly increased bone mineral density after 6 months (P <0.05), unlike the alendronate patient group (P = 0.51).

ORIGINAL ARTICLE Yue, J. *et al.* Repair of bone erosion in rheumatoid arthritis by denosumab: a high-resolution peripheral quantitative computed tomography study. *Arthritis Care Res. (Hoboken)* http://dx.doi.org/10.1002/acr.23133 (2016)