

"Ultrasound in the management of rheumatoid arthritis: ARCTIC randomised controlled strategy trial"

Response to:

Points to be addressed as of July 4th 2016:

Comment 1.

Thank you very much for your detailed response to our queries. We understand and appreciate that all the outcomes you report were pre-specified in the original protocol. The fact remains, however, that there are discrepancies between the trial registry and the protocol/ final paper. Can you please add text to the reporting of the secondary outcomes in the paper (Around Table 2) where you explain that these outcomes (Please mention them specifically) were prespecified in the original protocol, but erroneously not added to the (first version of the) trial registry.

Response 1:

We do agree that there are discrepancies between the information provided in the trial registry registered before the initiation of the trial (September 20, 2010), and the protocol/final paper/statistical analyses plan (SAP). Our impression was that the detailed pre-specified analyses of secondary outcomes should be described in the SAP and/or protocol, and that the secondary outcomes in the trial registry should include the key secondary outcomes of the study. We will acknowledge the discrepancies in the manuscript.

Action 1:

We have added the information requested by the editor concerning these outcomes (listed in the file "SecondaryoutcomesreportinginBMJ.pdf") below table 2, with a symbol "I" that indicates "Outcomes not listed in the ClinicalTrials.gov registry on September 20, 2010 (prior to patient enrolment), but described either in trial protocol and/or statistical analyses plan prior to database lock and analyses (online supplement)."

Comment 2:

Please also add some text on the outcomes that were listed in the trial registry, but not reported in the paper (Magnetic Resonance Imaging (MRI) of dominant hand at 12 and 24 months; Work performance at 12 and 24 months (WPAI) and Medical Outcomes Study Short Form 36 item (SF36); Dual Energy X-ray Absorptiometry (DEXA) of spine and hip), and provide a short explanation.

Response and action 2:

We have added the following statement in the section "Outcomes" on p. 9-10: "A subset of the pre-specified outcomes is not reported, either due to feasibility issues or because the methodology and interpretation of results would be beyond the scope of the current paper (i.e. Magnetic Resonance Imaging outcomes, Work Productivity and Activity Impairment outcomes, Dual Energy X-ray Absorptiometry outcomes and outcomes from the Medical Outcomes Study Short Form 36 item). The results of these analyses will be published in full

in more specialized journals and provided in the ClinicalTrials.gov database (NCT01205854).”

Comment 3:

Thank you for pointing out that you mentioned the earlier abstract in your original cover letter. “The data have previously been presented as a late-breaking abstract at the Annual Meeting of the American College of Rheumatology in San Francisco (November 10th 2015).” Please do as you suggested and include a statement of this publication and the recent EULAR congress in London, June 9th 2016 at the end of the manuscript.

Response and action 3:

We have included a statement on “Preliminary reports”, referring to this term as outlined in the ICMJE statement on Overlapping Publications (<http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/overlapping-publications.html>): “Preliminary reports of the ARCTIC trial have been presented at the Annual Meeting of the American College of Rheumatology in San Francisco (November 10th 2015) and the European League Against Rheumatism (EULAR) annual congress in London (June 9th 2016).“