Author’s response to reviews

Title: The ANKLE TRIAL (ANKLE TReatment after Injuries of the Ankle Ligaments): what is the benefit of external support devices in the functional treatment of acute ankle sprain? : a randomised controlled trial

Authors:

Suzanne Witjes (suzanne.witjes@gmail.com)
Femke Gresnigt (femkegres@hotmail.com)
Michel PJ van den Bekerom (bekerom@gmail.com)
Jan G Olsman (j.olsman@jbz.nl)
Niek C van Dijk (c.n.vandijk@amc.uva.nl)

Version: 4 Date: 28 November 2011

Author’s response to reviews: see over
Amsterdam, 28 November 2011

Concerns: Third revised manuscript of study protocol randomized controlled trial ANKLE TRIAL (MS: 4138964585132804)

Dear Editor,

We are pleased to send you the third revised manuscript of our study protocol, after reading and discussing the last comments of dr. Carl J. Lombard to our second revised manuscript.

In the first place we would like to thank dr. Lombard for approving the sample size analysis. His last comments concerned the description of the statistical analysis. After consulting Inger Sierevelt, our researcher with much knowledge about statistics, I revised the description of the statistical analysis, according to his comments:

‘Baseline characteristics will be presented using descriptive statistics; continuous data will be summarized as mean and standard deviation in case of normal distribution, or as median and range when distribution is skewed. Categorical data will be presented a frequencies and proportions. The primary analysis will be performed on the main outcome measure of this study, the Karlsson score, at 6 months follow-up. The treatment groups will be compared using an ANOVA test with post hoc pairwise comparisons (with Bonferrini correction).

Due to the repeated datastructure, secondary analyses will be performed using linear mixed models on the Karlsson score, FAOS score and VAS scores (change from baseline) to estimate change as a function of time and mean differences between the treatment groups. Akaike Information Criteria (AIC) will be used as an indicator for model fit. The number of recurrent ankle injuries and adverse events will be analyzed using a $X^2$ test or log-rank test, when appropriate. Analyses will be based on the intention-to-treat principle and performed in PASW statistics 18 (SPSS Inc. Chicago, IL). Statistical uncertainty will be quantified by 95% confidence intervals.’
This statistic analysis description can be found at page 8 of the manuscript, in which I also highlighted all made changes in yellow.

I hope this third revised version of the manuscript will now be suitable for publication in the journal BMC Musculoskeletal Disorders. As far as we know the ANKLE TRIAL is the first randomized controlled trial (which follows the CONSORT statement) in which two functional treatment strategies with external support are compared to a control group without any form of external support. So results of this study, which will follow in nearby future, could lead to a changed view on treatment of acute ankle sprains.

We hope to hear from you soon.

Yours sincerely,

Suzanne Witjes
(on behalf of co-authors Gresnigt, Van den Bekerom, Olsman and Van Dijk)