Reviewer's report

Title: Displaced midshaft fractures of the clavicle: non-operative treatment versus plate fixation (Sleutel-TRIAL). A multicentre Randomised Controlled Trial.

Version: 1 Date: 9 July 2011

Reviewer: Michael Zlowodzki

Reviewer's report:

I congratulate you to your considerable efforts in trying to answer an important clinical question. Overall that is a pretty good study protocol. I truly hope you will be successful in pulling this off. In my opinion the only critical point is your primary outcome.

Firstly, you say that your primary outcome is symptomatic nonunion as opposed to just a nonunion. However you do not describe in your protocol what "symptomatic" means. I would probably just stick with nonunion for the sake of the primary outcome. I would regard it as a nice bonus if you end up having enough good data to actually analyze symptomatic versus non-symptomatic nonunions but limiting a negative outcome to a symptomatic nonunion will make this study more difficult and will increase the required sample size.

Secondly you say that fracture union “will be determined objectively on X-rays”. That is not nearly as objective as you might think. I would advice to adjudicate potential nonunions by multiple surgeons. That would greatly strengthen your study.

Furthermore I highly recommend doing a pilot study to see if your plan is feasible. Enrolling patients in a non-operative versus operative treatment RCT is very challenging. A lot of patients might not consent to it. While Michael McKee’s group was very successful conducting such a trial, others have tried and had to give up. The process of consenting the patients has to be very well thought out. Make sure you that you plan well how to present this study to eligible patients.

Good luck!

Level of interest: An exceptional article

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests