Reviewer’s report

Title: ORCHID: Open reduction and internal fixation versus casting for highly comminuted intra-articular fractures of the distal radius in elderly patients - A randomized clinical multi-center trial

Version: 2 Date: 4 June 2010

Reviewer: Jonathan Alistair Cook

Reviewer’s report:

General
The protocol is for a large trial which compares medical versus surgical of treatment for distal radial fractures in elderly patients. The study is well thought out and the protocol is well developed and the investigators are to be congratulated on seeking to conduct a key patient relevant piece of research. I have no major revisions to suggestion and only a number of minor points where important details are either missing or I think further clarity would be advantageous.

Minor Essential revisions
1. Recruitment
There is no mention of the expected recruitment rate and number of centre in the main text. Basic information presented in the abstract but this should be in the main body of the protocol and it would be useful to give other details like expected proportion eligible patient who are randomized and the type of centres which will be recruited.

2. Randomisation
The protocol states the timing of randomisation is ‘before intervention’. It is not clear from this what is planned. Randomisation would by definition have to occur before the intervention (to be able to deliver the randomised treatment). This is very important issue and the protocol should be more specific about where it will occur and what stage in the care pathway. Related it is not clear who will make sure the patient is allocated (is it the responsibility surgeon, a nurse?)

3. Data collection
It is not clear how some of the outcomes are being collected. Presumably the SF-36 and the DASH outcome are by patient completed questionnaire. Please state this if so. How would such a questionnaire be administered to the participants? Will it be handed out at the outpatient visit and completed in the clinic? Or is it posted out and/or back to the trial centre?

4. Treatment definitions
Extensive criteria are mentioned for the patient included in the study. No mention is made (bar a reference to learning) about who will deliver the surgical treatment. I note that this is a pragmatic trial and there is likely to be a mixture of surgeon with reference to experience, training, clinical specialism. This is fine and appropriate in my opinion but I think it would be useful to state this (if this is the case) and if there are someone obviously minimum criteria these should be given.

The protocol states “Every study center is allowed to perform the interventions according to its house standard… , so that no surgical learning curves due to specific implants or techniques are expected.” In my opinion this statement is not correct in the sense that there will presumably be a mixture of expertise and experience in surgeons delivering the surgical intervention. Surgeons delivering the surgical treatment will be those who would undertake the intervention in standard clinical practice. Arguably, no surgeon ever has no learning (as even after a very large number of cases they may still be refining and learning) but the bulk of expertise has been acquired. Perhaps the authors mean simply that the surgeons delivering the surgical treatment will be familiar with the implants used? I would suggest this statement is revised according along the above lines as appropriate to the studies planning.

It is not clear to me who will deliver the conservative treatment. Information on this should be stated explicitly.

Discretionary Revisions

1. Outcomes
The secondary outcome of self-employment seems (at least in English) as strange choice particularly for an elderly population. The definition also would be worth further clarification/consideration as it seems to refer to a composite with mortality and also in change of status. Would something like ability to work not be a better outcome?

2. Sample size
It would be helpful to reference the Walter suggested MCRD of 2.5 for SF-36.

3. Analysis
It would be preferably to state what is intended by ‘ITT’ when it is referred to. It would appear in the primary analysis it is often called a ‘complete case ITT analysis’. I think the protocol should be explicit about this with regards to the main (‘confirmatory’) analysis.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests