Reviewer’s report

Title: Comparison of outcome measures and complication rates following three different approaches for Primary Total Hip Arthroplasty. Study Protocol for a randomized controlled trial.

Version: 0 Date: 25 Nov 2017

Reviewer: Andrew Duckworth

Reviewer’s report:

General comments:

Many thanks for asking me to review this manuscript. It is a proposal for a prospective randomised single centre superiority three-arm trial comparing the patient reported outcome (Oxford Hip Score) in adult patients undergoing a total hip replacement for osteoarthritis through either an anterior, direct lateral or posterior approach.

I would like to commend the authors on the presentation of the manuscript and the level of detail presented. Clearly a great deal of time and effort has gone into the planning of this trial. With regards to the question being asked, without doubt this would be of interest to the orthopaedic community. Much of the debate in the past has been comparing the direct lateral with the posterior approach and there remain staunch advocates for both as the literature remains inconclusive as both methods have positive and negative aspects. The anterior approach is certainly growing in popularity and there are potential merits reported in the literature. An ambitious three arm trial comparing these three approaches is needed.

Many of my concerns regarding how the trial would be setup, controlling for surgeon bias and expertise (which would be a major limiting factor in many centres) appear to have been addressed well. I have some minor concerns regarding this, which I have noted below in the specific comments.

One concern I do have though is regarding the primary outcome measure. I fully appreciate the importance of using a patient reported outcome measure as the primary outcome and OHS is the natural choice. However, the OHS at 24 months post-surgery in this number of patients is always unlikely to find a difference. From reading your manuscript and my understanding of the current literature, some of the key arguments regarding these approaches are early post-operative mobility (due to abductor dysfunction with the direct lateral approach), dislocation rates and length of stay. Using the OHS at 2 years is unlikely to pick this up. I wonder whether using the OHS at 6 months would be better?

Specific comments:

Abstract, Lines 18-19: need to state clearly what and when the primary outcome measure is.
Abstract, Line 20: be clear VAS is related to pain.

Background, Lines 12-17: I think this data is interesting but is quite repetitive and could be cut down.

Background, Line 30: be consistent throughout and use either direct lateral or Hardinge approach

Background, Lines 44-45: this sentence repeats detail from early sentence in paragraph and could be removed.

Methods, Lines 69-70: be robust with the approach as this is key to recruiting

Methods, Lines 76-79: do you just mean primary OA? Would OA secondary to trauma be included? Would OA secondary to RA be included?

Methods, Lines 86-90: do you foresee any issues with recruitment/withdrawal if a patient is seen by surgeon A in clinic who does posterior approach, agrees to enrol and is recruited, then is randomised to anterior under a different surgeon?

Methods, Lines 92-94: I am unclear of the importance of pre-op blinding without post-op blinding? Could researchers assessing patients be blinded when doing the outcome assessment?

Methods, Lines 115-117: Need to specify at what time point

Statistical considerations, Lines 188-192: Is it worth also stratifying by age, gender and surgeon?

Statistical considerations, Line 208: The statistical methods and power analysis seem very sound. I just wonder why 80% power and not 90% power was chosen?

**Level of interest**
 Please indicate how interesting you found the manuscript:

- An article of importance in its field

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