Reviewer's report

Title: Study Protocol: Intrathecal opioid versus ultrasound guided fascia iliaca plane block for analgesia after primary hip arthroplasty - a randomised controlled trial

Version: 1 Date: 13 December 2010

Reviewer: David Moher

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This is a protocol of a randomized trial comparing ultrasound block to no ultrasound block in 96 people receiving primary hip arthroplasty. The primary outcome is 24-hour post operative morphine consumption.

Page numbering, and better still line numbering would greatly facilitate my peer review of the protocol.

The protocol is registered and the investigators are seeking funds. On this latter point, can the investigators provide a little more detail for readers about the funding request? For example, are the investigators applying for peer review funding, funding from industry, or a combination?

In the covering letter submitted along with the protocol the investigators consider this to be a pragmatic trial. I’m more used to thinking about pragmatic trials as ones involving several hundred participants across many different centres recruiting participants.

In the body of the protocol (hypothesis section) the investigators state their interest in seeing whether ultrasound guided versus non-ultrasound block is “comparable”. When I read comparable in the context of a randomised trial I interpret this to mean interest in detecting equivalence or non-inferiority. The investigators need to clarify this point as it impinges upon several other aspects of the proposed trial, particularly the sample size section. Is the trial designed as a superiority trial or an equivalence or non-inferiority trial?

First line of the “overview” section: the investigators should delete “prospective” and elsewhere in the text of the protocol.

The consent section is rather long at about half a page. Is there something unusual about this trial, in terms of the intervention, safety profile that warrants this amount of space?

The randomisation section needs more clarification for readers. The investigators tell readers about how the generation of their sequence will be generated – computer generated. What’s less well described is how allocation concealment is be achieved and how the randomization will be implemented (e.g., Moher et al. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomized trials. BMJ. 2010 Mar 23;340:c869)?

Would readers find it more helpful if group 1 and group 2 were relabelled
‘experimental’ and ‘control’?

In the sample size and statistical considerations section the reader is not provided with information about the anticipated length of time the investigators will take to recruit and enrol the participants – how long will the trial take? Similarly, in this section, there are no details as to whether the investigators plan on establishing a data safety and monitoring committee as part of the trial conduct?