Author's response to reviews

Title: Arthroscopic Partial Meniscectomy in Middle-Aged Patients with Mild or No Knee Osteoarthritis: A Protocol for a Double-Blind, Randomized Sham Controlled Multi-Centre Trial

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Author's response to reviews:

Response to reviewer

We thank you for the second review of our article. We have identified a number of comments noted by the reviewers. All these comments have been responded below.

Reviewer - Gunter Spahn

1. Comment

The title should clearly declare the study type! The reproof to the journals section isn’t good enough. The study type also should be identifiable in a PubMed search.

Response

We understand this need; if this is according to the editorial view of BMC we will change the title.

Action

The Title has been changed to: “Arthroscopic Partial Meniscectomy in Middle-Aged Patients with Mild or No Knee Osteoarthritis: A Protocol for a Double-Blind, Randomized Sham-Controlled Multi-Centre Trial”

2. Comment

In the abstract you don’t mention this limitation (Level 1 studies only). This must declared clearly! Response

“Level 1” does not refer to a limitation but to the usual description when reviewing the literature. One would and should always refer to highest quality studies.

Action

None

3. Reviewer Comment

Please be correct! This must be described also in the study protocol.
Response

We fail to see how further describing the evaluation of the screening stage and inclusion will contribute to the study protocol. As earlier stated it will be clearly and thoroughly described in our main article when the results are published. A flowchart has already been provided to the study protocol to give insight into the screening and inclusion process.

Author's Action
None

4. Comment

One more. You demonstrate a study protocol! Only patients with specific clinical meniscus tear and not with unspecific knee pain should be included. If you don’t make this differentiation the study is worthless. I you feel it unable to do thus, this study protocol shouldn’t be published.

Response

Again we must declare that no consensus exists on what defines a clinical meniscus tear compared to unspecific knee pain with an MRI confirmed meniscus tear. No clinical test has been shown to be accurate in diagnosing meniscus tears as defined by arthroscopy or by MR as shown by Hegedus et al. 2007 and many others [1-6]. In addition, there is a poor correlation between patient history and a meniscus tear [7, 8]. To ensure external validity all patients deemed eligible for arthroscopic surgery with an MRI confirmed medial meniscus lesion is included. Patients are asked about relevant symptoms and examined with McMurray test and joint line tenderness. All these findings are registered. These inclusion criteria’s has already been approved by the Research Ethics Committee of Region Zealand, Denmark and cannot be changed.

Action
None

5. Comment

One more! If you perform other “treatments as indicated” should describe your indications!

Response

The arthroscopic intervention is described as “Intervention A” in the article. Any other findings by the surgeon, i.e. other than meniscus lesion, will be treated at the discretion of the surgeon. We have elected not to have a pre-specified protocol for other interventions, but rather let the individual surgeon decide. All other arthroscopic procedures are described and registered.

Action
None

6. Comment

In your final analysis you have to perform a inter-surgeon comparison! But this has also been declared in the study protocol also.
Response

We will evaluate the results with a mixed effects model, where “surgeon” will be included as any other variable (e.g. age, gender weight etc). The purpose is not to specifically compare the results by different surgeons.

Action

None

7. Comment

This is unacceptable and a bias to your “treatments as indicated”. Young patients with a buckle-handle” tear should be undergone reconstruction.

Response

Despite lack of scientific evidence, we agree that a buckle-handle tear sustained during a significant trauma and resulting in mechanical problems in a young patient should be sutured, if possible. In this study however, we include a middle-aged population aged 35-55 without significant trauma, i.e. a very different group of patients. Although bucket-handle tears are not expected to appear in the current middle-aged patient group we acknowledge the need for exclusion of patients with bucket-handle tears. The current wording is: “Patients will be excluded if they are in need of acute surgery e.g. locking knees or high-energy trauma.” Considering that locking knees and high-energy trauma are the result and cause of bucket-handle tears and since the current wording is approved by the ethics committee, we are reluctant to change the wording.

Action

None

Reviewer – Morgan Jones

1. Comment

I still think that the authors overstate the impact that their results should have if they show no difference between groups. Certainly every other aspect of their design is outstanding and should impact clinical practice. However, I don't think that the orthopaedic community will accept no difference as a strong enough piece of evidence to stop operating on younger patients with meniscal tear and mild OA. However, a finding of superiority for arthroscopy would certainly increase the tendency to treat these patients surgically, and a finding of superiority for sham would discourage operative treatment.

Response

We agree that showing no difference between APM and placebo might not be as convincing to the orthopedic community.

Action

We have changed the discussion on page 10 to: “If, on the other hand, our results indicate that the efficacy of APM is less than placebo (and it may do more harm), then this would also significantly impact upon current practice and APM should not be the treatment of choice in middle-aged patients with an
MRI-verified meniscus tear and mild or no knee osteoarthritis. No difference between APM and placebo might not be regarded as a strong enough piece of evidence to stop operating on middle-aged patients with meniscus tear and mild OA. However, a finding of superiority for arthroscopy would certainly increase the tendency to treat these patients surgically, and a finding of superiority for placebo would discourage operative treatment.”

References