Reviewer’s report

Title: Does surgery followed by physiotherapy improve short and long term outcome for patients with atraumatic shoulder instability compared with physiotherapy alone? Protocol for a randomized controlled clinical trial

Version: 4 Date: 11 July 2014

Reviewer: J. Michael Wiater, MD

Reviewer’s report:

The authors present a revised protocol for a multi-center prospective, randomized controlled trial evaluating the effectiveness of capsulolabral repair in patients with atraumatic shoulder instability. The protocol has been revised in response to previous review. Many previous issues have been clarified in the protocol. However, a few concerns still remain. Overall the protocol is focused toward the study of its intended purpose. The discussion and referencing of supporting literature is appropriate.

Please provide explanation for the following issues:

Major Compulsory Revisions

1. The definition of included patients with atraumatic instability: Background section defines shoulder dislocation as traumatic (even when not associated with high-energy trauma). Please include history of shoulder dislocation as an exclusion criteria in Participants section of protocol. Also, one of the secondary outcomes is number of shoulder dislocations. Please clarify this as postoperative dislocation. I suspect this would be rare in those with no previous dislocation, and in patients with no prior dislocation this is possibly iatrogenic.

2. The definition of what qualifies as capsulolabral injury is never defined. Please be more specific about labral tears, or capsular tears/avulsions. Does this include SLAP tears? This would eliminate patients with “redundant” capsule from receiving any stabilization procedures, as this does not reliably constitute damage. There should be a defineable lesion to determine patient assignment to randomization.

3. Again, stating that “participation in this clinical trial will not entail additional risks beyond those associated with standard care options for atraumatic shoulder instability” is not accurate. There are other modalities than arthroscopy to evaluate these patients for capsulolabral damage. While you added “risks associated with orthopaedic surgery under general anesthesia,” the risks were not defined. Also, this does constitute additional risk to patients that could be assessed otherwise with MRI. The standard care options for patients with atraumatic shoulder instability do not include diagnostic arthroscopy. In fact, this is the exception rather than the standard, performed when other care options as physiotherapy or MRI have failed to improve the symptoms or determine a diagnosis.
The alternative to your protocol, to be sham-controlled, is to determine patients with capsulolabral damage on MRI, ultrasound, or arthrography. If they are determined to have some damaged structure, inclusion criteria would be met and arthroscopy could then be performed. The true sham procedure would be arthroscopy without repair, versus the alternative stabilization procedures. This eliminates added risk to patients with atraumatic instability and no capsulolabral damage.

4. There is no mention of postoperative clinical assessment, other than those done by blinded research assistants. When will these patients be assessed clinically for reasonable monitoring for postoperative complications such as infection, neurologic injury, stiffness, etc. There are safety concerns in these patients, though complications will likely be rare.

Minor Essential Revisions
1. Please make clear if you are including patients of all age groups and activity levels.

Discretionary Revisions
1. Please mention that you will record data on pathology variations by location, tear size, and type of repair (number of anchors, all-arthroscopic, types of suture fixation).

Level of interest: An article of importance in its field

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.