Reviewer's report

Title: The Patella pro study - Effect of a knee brace for treatment of the patellofemoral pain syndrome (PFPS): Design of a randomized clinical trial [DRKS-ID: DRKS00003291]

Version: 1 Date: 25 July 2013

Reviewer: Marco Paoloni

Reviewer's report:

• Major Compulsory Revisions

1. Methods

1.1. In- and exclusion criteria

1.1.1. The Authors should clarify if the pain level (e.g. with a cut-off previously defined on a VAS score) represents an inclusion criteria or if they will consider eligible for the study patients whatever their pain level.

1.1.2. Please correctly define 3° to 4° osteoarthritis (which is the grading scale, in this case?)

1.1.3. Please correctly define local cartilage damage 3° to 4° (which is the grading scale, in this case?)

1.1.4. The Authors should better clarify the sentence “These diagnoses are made on the basis of medical history, based on clinical findings and on the basis of existing X-ray and MRI scans.”. Does it mean that without existing X-ray and/or MRI scans patients would not be recruited? This could represent a selection bias, as only those patients with a greater attention about their pathological condition would be selected.

1.2. Intervention

1.2.1. The proposed exercises program (Patella move) should foresee a gradualness of intensity, which should be individually set, mostly on the basis of patients’ actual symptoms. It’s a common observation, in fact, that PFPS patients generally are not able to perform some kinds of exercises (One-legged stance and squat, and 5. One-legged stance and lateral pressure) in the first phases of their rehabilitation period. Moreover, as the Authors aim to include patients 18 to 50 years, older patients may have more difficulties in performing such intense exercises. Please clarify.

1.2.2. The supervised exercise program has not been well described. Please provide a more detailed description about what patients will do in a physiotherapy setting. Are physical therapies prescription foreseen? Please clarify.

1.3. Outcome parameters

1.3.1. Primary outcome measure should refer to the outcome measure used for sample size calculation
1.3.2. The Authors should better describe all the outcome measures they are using (e.g. please define the content of the 7-points Likert scale).

1.3.3. Please consider to correctly define which are the expected results from the present study.

2. Discussion

2.1. The Authors state that “The trial started in 2011 and is expected to finish in June 2013”. This is apparently in contrast with the definition of recruitment period (April 2012-October 2013). Please clarify. The same applies to Discussion paragraph in the Abstract (“This trial started in Oktober 2011 and will finish in Oktober 2013”).

• Minor Essential Revisions

3. Abstract

3.1. “Oktober” should be “October”

4. Background

4.1. 2nd paragraph, line 5: I have some concerns about the definition of PFPS as a diagnosis of exclusion. Despite being true that pathological changes in articular cartilage normally do not occur, it should be stressed that some characteristics of PFPS (e.g. misalignment, patellar maltracking) can be detected by clinical examination and guide to the diagnosis of this pathological condition (Witvrouw, E., Werner, S., Mikkelsen, C., Van Tiggelen, D., Vandenberghe, L., Cerulli, G., 2005. Clinical classification of patellofemoral pain syndrome: guidelines for non-operative treatment. Knee Surgery, Sports Traumatology, Arthroscopy 13, 122–130)

4.2. “metaanalysis/ meta-analysis”. Please be homogenous in terms selection

4.3. Please would the Authors briefly specify which are the main characteristics of Patella PRO brace, that allow them to consider it different from other braces already used in clinical trials.

5. Methods

5.1. Study centers

5.1.1. “parameter” should be “parameters”

5.2. Patients selection

5.2.1. please would the Authors confirm that the recruitment period is correct (April 2012 – October 2013)

• Discretionary Revisions

6. Background

6.1. 3rd paragraph, line 10: “on the contrary” could be deleted

**Level of interest:** An article of importance in its field
Quality of written English: Needs some language corrections before being published

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