Reviewer's report

Title: The effect of concentrated bone marrow aspirate in operative treatment of fifth metatarsal stress fractures; a double-blind randomized controlled trial

Version: 3 Date: 27 February 2015

Reviewer: Luisa Trombi

Reviewer's report:

A) Advices regarding the study protocol asked by the Editor:

BMC Musculoskeletal Disorders does publish protocols of proposed or ongoing research. Protocols should provide a detailed account of the hypothesis, rationale and methodology of the study, and protocols for randomized controlled trials should follow the CONSORT guidelines (http://www.biomedcentral.com/1471-2288/1/2).

I appreciate how the authors designed the study, reducing variability due to different type of (stress) fractures, and using the same fracture fixation for all the patients and for both groups. However, there are some details that need to be included in the protocol as the CONSORT guidelines recommend (see items in table 1 in http://www.biomedcentral.com/1471-2288/1/2).

Briefly:

Item 1) Ok


All the acronyms in the manuscript have to be defined (cB, cBMA, etc) separately from those in the abstract. To be exactly reproducible, precise explanation of “cB” is needed: is concentrated blood from peripheral blood (line 129)? Is it Platelet Rich Plasma? If yes, the authors need to explain the procedure with more details (how concentrated blood is achieved? How many milliliters?). It’d be useful referring to the device’s brochure.

Item 3) Specify the name of the local institution review board, with the approval date and number, if existing. Specify where the data will be collected and who has got the passwords for the data base. Please, specify any procedural changes if minors will be enrolled.

Item 4) Give precise details of the intervention for each group, and how long since the diagnosis the intervention will be administrated.

Item 5) State objectives and hypothesis in a dedicated paragraph in the Methods section.

Item 6) Ok
Item 7) Ok
Item 8) Ok
Item 9) Concealment criteria should be better clarified.
Item 10) Ok
Item 11) Ok
Item 12) Ok
Item 13) Add a brief Results (i.e., expected results) section to the protocol. Show a flow diagram.
Item 14) Place the paragraph “Data acquisition and follow-up” as a part of the Results section. Define enrollment period.
Item 15) Not to be reported now.
Item 16) Not to be reported now.
Item 17) Not to be reported now.
Item 18) Not to be reported now.
Item 19) Ok. Place “Adverse events” paragraph as a part of the Results section.
Item 20) Ok
Item 21) Ok
Item 22) Ok

B) Specific questions asked by the Editor:

1) Will the study design adequately test the hypothesis?
Yes. In my opinion, the protocol could be a good opportunity to evaluate the effects of bone marrow cells on the healing of stress fractures, both for MT-V ones and for other type of fractures.

2) Are sufficient details provided to allow replication of the work or comparison with related analyses: if not, what is missing?
No. The method for cell and blood concentrate preparation is not sufficiently described to be replicated. Moreover, the acronym “cB” is unclear. Do the authors refer to PRP or other blood fractions? The intervention has not be well described.

3) Is the planned statistical analysis appropriate?
Yes.

4) Is the writing acceptable?
Yes.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable
Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare I have not competing interests regarding this manuscript