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: 21 December 2014

Reviewer: Stuart Warden

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The current submission reports the protocol for a double-blind randomized controlled trial of the efficacy of bone marrow aspirate on the healing of operatively treated stress fractures of the fifth metatarsal. Being the protocol for a study which has possibly already commenced enrollment, there is likely little the investigators can do with regards to modifying their protocol. However, two protocol features that warrant consideration are:

1) The harvest of bone marrow for active treatment group only. While a sham procedure is being performed in the control group wherein a skin incision will be made, no bone marrow will be collected. Please consider also collecting bone marrow in the control group to reproduce exactly the same procedure as being used in the active group. This will promote blinding and heighten group comparability.

2) Use of an internal bone graft as a natural scaffold in the active group only. If the purpose of the study is to explore the efficacy of the bone marrow aspirate, the groups should be treated identically apart from the aspirate. Thus, an internal bone graft should also be used in the control group. To that end, it would also be possible to blind the surgeons by having a operating staff member be in charge of providing the surgeon with either the bone marrow product or an inert substitute. That way you are comparing apples-to-apples in that patients are getting exactly the same management minus the active treatment.

Line 132 - will patients receive exactly the same or just 'similar' rehabilitation protocols?

Line 133 - change 'than' to ' then'

Line 160 - is the resumption of weight-bearing sports only? Subjects should be able to start swimming earlier if they desire.

Line 253 - in addition to Student's t-tests, consider

MINOR REVISIONS

Line 51 - change 'sports mentality' to 'sports participation'

Line 53 - do you have a reference for '...these fractures are more frequently diagnosed'?
Line 75 - change 'union is assessed' to 'union will be assessed' (change other instances within the manuscript from current tense (i.e. 'is') to future tense (i.e. 'will be')).

Line 99 - further details are required with regard to the inclusion/exclusion criteria. For instance, is there certain duration of symptoms after which patients will be ineligible to participate, could the patients have received previous treatment, will delayed- and non-united stress fractures be included?

Line 105 - do you mean 'Current participation in another clinical trial'?

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

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