Reviewer's report

Title: Clinical Evaluation of Short 6-mm Implants alone, Short 8-mm Implants combined with osteotome sinus floor elevation and Standard 10-mm Implants combined with osteotome sinus floor elevation in posterior maxillae: study protocol for a randomized controlled clinical trial.

Version: 1 Date: 17 May 2015

Reviewer: Raphael de Souza

Reviewer's report:

This is an interesting trial protocol that will add some relevant results for the oral health field. Please check my comments below:

Major Compulsory Revisions:

P.3, Abstract and P.9, Methods: The selection of a single implant for each participant for statistical evaluation does not seem to be appropriate, as long as some information could be considered in statistical analysis by using different methods. I strongly recommend to change planned methods and get a statistician to provide support for planning this part. Some statistical methods (such as generalized estimating equations) may be used for taking every implant placed into account with considering the paired effect of having two or more in a single participant. This will lead to a more precise testing protocol and avoid losing relevant data from study participants. Revising tests will be useful, as exemplified by saying that an ANOVA would be used for the study (if some outcomes are binary, an ANOVA would not be employable; other methods should have been taken into account).

Considering that sample size was based on a binary outcome, I consider that 225 participants may not suffice for detecting a difference of 1.6%. Please clearly state what the minimally important difference considered is, and revise this estimation with a statistician.

The Methods section provides too little details regarding several procedures. They must be dealt with in order to achieve a reproducible study protocol:

1- How will the authors define what “systemically healthy adults” are? Is there any type of disease that will be overlooked, such as controlled type 2 diabetes mellitus or hypertension? If positive, do you not think it would be interesting to report how many people/group have such diseases? If negative, I wonder if recruiting enough participants will be viable.

2- Please define partial edentulism better for inclusion purposes. Do you consider a single remaining maxillary tooth as adequate for inclusion? Or shall participants present all incisors and canines?

3- Please explain how the edentulous ridge will be measured? Do you intend to use CT scans, panoramic radiographs, and/or other methods? For item “d” of the
inclusion criteria, how much is sufficient width (e.g., 6 mm or more)?

Minor Essential Revisions:
There are several parts of the text in need of English revision.
P.1: The expression “randomized controlled clinical trial” can be reduced to “randomized controlled trial” in the title and further appearances.
P.2-3: Abstract:
In the background: “recent”, not “resent”; you must mention “success rate” or “survival rate” on the 3rd line. On 4th line: “are less technically demanding”. I recommend citing which level of evidence is missing for the mentioned comparison; rewrite the sentence “which is the focus of the proposed study”.
Methods: simplify the sentence “using randomization tables allocating the patient a number with a corresponding envelope” by mentioning something like “according to a table of random numbers”. You should mention which are the patient-reported outcomes considered, the term refers to a category of outcomes, not to a specific construct. It is “3”groups, not “43” for ANOVA.
Discussion: I suggest rewriting this part in order to make it clearer. My suggestion is something like “The results of the trial will support better decision-making for dental implant treatment in atrophic posterior maxillary ridges. If favorable, the use of short implant may avoid adjunct procedures used of implant insertion, thus reducing operative time, complexity and postoperative discomfort.”
Background, P.4:
Mention the meaning of the acronym “OSFE” in the 1st paragraph. The 3rd paragraph only mentions a “similar rate” but does not say if it is a success rate or something else.
You should be clearer regarding how you can affirm that there are only two randomized trials comparing shorter versus longer implants in the atrophic posterior maxilla. Please explicitly say that those studies were found by the two systematic reviews cited in this section; if not, please describe how you can say that there are only two RCT, .e.g, by explaining that you have run a structured search in some databases and selected studies by using systematic methods.
Objective and hypotheses:
This part should provide the PICO components in a clearer form. Please consider the following structure: “The aim of the randomized controlled trial is to evaluate the efficacy of short implants (6mm) alone and short implants (8mm) combined with osteotome sinus floor elevation, compared to standard implants (10mm) combined with osteotome sinus floor elevation (OSFE) for treating atrophic posterior maxillary ridges of partially edentulous adults. Considered outcomes include … (then, mention each considered outcome).”
Methods and Design:
Move “sample size” estimation to the end of the section, i.e., after the “outcomes”. Authors should explicitly cite which the primary outcome is.
Please provide more details about the surgical procedures. Which implant type (model, manufacturer…) will be used? The OSFE procedure needs more explanation or at least a reference for a detailed description. Please provide the name of the anti-inflammatory drugs, as well as prescription details (doses, time spam, et cetera) for all medications to be used. Which concentration of the chlorhexidine mouthrinse will be used, and what is the reason for 5-6 uses per day instead of twice/day as usual? Will authors use a single- or two-stage protocol with delayed load? What material will be used of fabricating crowns and bridges, as well as abutments? Authors could provide more details about the questions posed for the patients, such as an English translation with original files in Chinese in a supplementary material.

On P. 8: there may be a better word than “flush”.

Follow-up: Please explain which criteria for success and survival will be used in this study. The same should be provided for the complications to be considered, instead of just saying biological and mechanical complications. Do you intend to evaluate bone level by using certain types of radiographs with/without positioning devices (please describe intended methods).

The Discussion section could become even more interesting if authors provide data regarding potential benefits associated with possible results. Moreover, the information regarding Straumann implants apparently contradicts the Introduction section. Please provide details regarding implant type used in the mentioned studies or other relevant aspects for both sections, so the reader can distinguish potential reasons for discrepant results.

“Trial status”: Please correct “clinicaltrials.org”.

Discretionary Revisions:

Background: Please consider the provision of a paragraph that briefly explains the epidemiological aspects of the clinical issue approached by your protocol. You could mention that partial tooth loss is highly prevalent in different populations worldwide, that the posterior area is more vulnerable and the percent of cases that will not have sufficient ridge height for restoration by implants in the posterior maxilla. This will provide the reader with a better view of how important this clinical issue is.

It would be interesting to cite a protocol number provided by the Shanghai Ninth People Hospital’s Ethics Committee.

Please use the term “participants” rather than “subjects” or other throughout the protocol, whenever applicable. The first is more accurate.

Item “d” of the exclusion criteria is redundant and could be removed. Perhaps authors might prefer to say that unfavorable prognosis/a possible indication of extractions that can result in anterior edentulism will lead to exclusion.

Withdrawals: you could add the sentence “requested by them” following “any treatment”.

The order of letters in the acronyms mentioned on the Authors’ contribution” section could be the same used in the byline.
Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests