Reviewer’s report

Title: Effects of vitamin D supplementation on liver fibro-genic factors in non-alcoholic fatty liver patients with steatohepatitis: study protocol for a randomized clinical trial

Version: 0 Date: 02 Dec 2018

Reviewer: Thomas Hiemstra

Reviewer’s report:

The authors present the design of a randomised controlled proof of concept trial.

In principle the submission is acceptable for publication and the study is of interest. However, a number of factors deserve attention before it can be recommended for publication:

1) There are multiple linguistic and grammatical errors which need to be addressed. The manuscript would benefit from review by a native English speaker.

2) The protocol proposes to assess safety by measuring PTH. A change in PTH in either direction will not inform safety; for this, the authors would need to monitor calcium concentrations in blood.

3) Sample size calculations are alluded to based on laminin as a candidate outcome measure. However, the data from which these sample size calculations have been derived are not provided, making it impossible to reproduce the authors' sample size estimates.

4) The statistical analysis plan requires more detail. There is a description of comparison of baseline variables by t-test or chi-square. First, given the randomised design, baseline variables should not be compared in this manner and p-values should not be reported. Second, although the authors describe the use of a test for normality they proceed to describe only a parametric test. Some variables are already known to be non-parametrically distributed, for example PTH. How will these be compared?

5) Greater clarity is required regarding the randomisation procedure. It is not clear to this reviewer whether the authors are proposing stratified randomisation, minimisation or block randomisation. Furthermore the authors state that randomisation will be 'carried out by a blinded researcher'. Is this randomisation or allocation? If the former, how will randomisation be carried out?

Level of interest
Please indicate how interesting you found the manuscript:

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Quality of written English
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