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

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Reviewer: Amit Goel

Reviewer’s report:

The research protocol under review, is for double blind RCT to examine the effects of vitamin D supplementation on liver fibrogenic factors in non-alcoholic fatty liver patients.

I have following comments

1. Patient population: The study is planned to include all NAFLD patients aged 20-60 year, who has been diagnosed with NAFLD for at least six months prior to enrolment in the study; diagnosis of fatty liver will be done based on findings from ultrasound reports. Inflammation and fibrosis are not of much relevant in those with bland NAFLD, usually detected on USG; inflammation nd fibrosis are of use in subset of NAFLD patients, known as NAFLD with steatohepatitis (NASH). Hence to make the results more relevant, I will suggest including only those NAFLD who have NASH.

2. Sample size: SS calculation is done on the basis of meta-analysis data on serum laminin; the objective of the study is not related to laminin hence it is not appropriate such sample size calculation; further the term laminin is not used anywhere in the manuscript which is referred for sample size calculation (J Gastroenterol Hepatol. 2016; 31(4):848-55). Hence SS need clarification

3. Randomization (i) as the authors have planned for stratified randomization based on sex and BMI, they will need calculated sample size for each subgroup of gender and BMI categories (ii) block randomization of two is inappropriate specially if you have more than two BMI subcategories; if block of two, after assigning treatment to the first person, assigned group for the second person is obvious, hence the block size shall be at least 4 or 6.

4. Long sentences which be shortened and several sentences could be joined into one to reduce the manuscript word count

5. Frequent spelling mistakes

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