Reviewer's report

Title: Study protocol: a randomized double-blind placebo-controlled trial of Classic Yin and Yang Tonic Formula for Osteopenia

Version: 4 Date: 13 June 2011

Reviewer: Kent Johnson

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The re-write of the manuscript (MS: 1725176005228941) is much improved. I have only a few suggestions, some referring to clarification of the content and others to style.

Page 1, Abstract, line 6: REPLACE “evaluate the efficacy and safety” WITH “evaluate the effect on BMD and the safety”

Page 2, line 1: please describe how “kidney deficiency in TCM” is defined
Page 2, line 2: REPLACE “controlled” WITH “control”

Page 2, last line: REPLACE “attractive” WITH “possible”

Page 3, line 7: INSERT “The” at sentence beginning with “present study”

Page 3, line 12: REPLACE “identified partially” WITH “partially identified”

Page 3, line 15: REPLACE “This trial will be” WITH “Subjects will be”

Page 3, lines 15, 16: REPLACE “to Shanghai” WITH “with Shanghai, & “to Fudan” WITH “with Fudan”

Page 3, line 20: DELETE “And” at beginning of sentence

Page 4, line 6: REPLACE “HbA1 cover” WITH “HbA1c >”

Page 4, lines 12-13: REPLACE “will be cause for exclusion” WITH “are also exclusion criteria”

Page 4, line 15: DELETE “consideration for the”
Page 4, line 16: DELETE “be”

Page 4, line 22: REPLACE “this” WITH these

Page 4, line 24: DELETE “placed”

Page 4, line 27: Clarify – Is everyone blinded? If not, who is not? State in text

Page 5, line 1: REPLACE “are” WITH “is”

Page 5, line 3: Should this be reference [1]? REPLACE “based on symptoms help” WITH “is based on symptoms and helps”

Page 5, line 20: neuro-endocrine should not be capitalized

Page 6, line 8: REPLACE “6 month” WITH “6 months”

Page 7, line 16: Reference [7] does not seem to be a reference about statistics / sample sizes. Define in text what the variables in the formula are. Sigma =, alpha
= , beta = , etc Page 7, line 18: Do you assume the SD of the BMD may be improved 0.125, or do you assume the mean of the BMD may be improved 0.125?

Page 8, line 20: REPLACE “endpoint efficacy” WITH “interest”