Reviewer’s report

Title: Beneficial effects of Korean red ginseng on lymphocyte DNA damage, antioxidant enzyme activity, and LDL oxidation in healthy participants: A randomized, double-blind, placebo-controlled trial

Version: 1 Date: 5 January 2012

Reviewer: Vladimir Vuksan

Reviewer’s report:

The manuscript entitled “Beneficial effects of Korean red ginseng on lymphocyte DNA damage, antioxidant enzyme activity, and LDL oxidation in healthy participants: A randomized, double-blind, placebo-controlled trial” aims to evaluate effect of Korean red Ginseng extract on oxidative stress in healthy patients. While the manuscript draws attention to growing need of evaluation of clinical efficacy of widely consumed natural health products, there are some concerns discussed below that need to be addressed.

Major:
The design of the clinical trial failed to set out primary and secondary outcome measures. The authors proposed an overly large number of outcome measures (blood pressure, BMI, Total cholesterol, LDL, triglycerides, DNA damage, plasma SOD activity, plasma GPx, plasma catalase activity, oxidized LDL, urinary 8-epi-PGF, BUN, creatinine, CBC, AST and ALT). In addition power analysis is not provided (what parameter is the power based on?). The rationale for certain measurements and their significance in the context of the trial is also missing.

Minor:
Abstract:
1. The terms SOD, GPx are not defined in the abstract. Abstract should be self-standing.

Background:
1. What is the reason the authors are evaluating healthy individuals instead of those with underlying pathology? The rationale should be provided.
2. The background should differentiate pre-clinical and clinical research when describing that ginseng “is known to exert” a number of effects.
3. Background focuses on listing effects of ginseng rather than provide brief general overview of present literature and more channeled rationale for study.

Test Capsule and Study design
1. What is the quantity of placebo used in the trial?
2. Were subjects who only used cigarettes or alcohol included in the trial? The statement should read: use of cigarettes and alcohol was not an exclusion.
criteria.

3. Are ten capsules taken at once after a meal of choice or spread out between 3 meals? This may introduce a confounding variable.

Assessment of dietary intake

1. What is the reason that participants continue their usual diet for only one week? Should it be for the duration of the study or during completion of a 3-day food record?

Anthropometric parameters, blood pressure

1. It would have been more accurate to measure blood pressure in triplicate. 20-min of rest is usually not necessary and 10 minutes would suffice.

2. Study measurements sections are too detailed in comparison to the protocol patients followed. The protocol does not state when the measurements are obtained, how many visits did participants have, when were each of the measurements taken.

Results/Discussion:

1. It is peculiar that none of the 69 subjects reported any adverse events for the duration of 8 weeks. The authors only reported on serious adverse events. However, nausea, hot flush and others listed are not to be considered as a serious adverse events (SAEs) as per ICH/GCP guidelines.

2. Figure 1 does not have a self-standing description accompanying the graph.

3. Discussion describes correlation between changes in plasma LDL and decrease in oxidative damage and urinary 8-epi-PGF2α; however, such correlation analysis have not been described in statistical methods section or results section. Is this correlation statistically significant?

4. The discussion drawing parallel between Korean red ginseng and American ginseng is not placed in the context of the trial and does not substantiate hypothesis in any way. It may be more appropriate to discuss differences between white and red varieties of Panax ginseng spp. in relation to oxidative stress.

Level of interest: An article of importance in its field

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

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

'I declare that I have no competing interests