Reviewer's report

Title: Can red yeast rice and olive extract improve lipid profile and cardiovascular risk in metabolic syndrome? A double blind, placebo controlled randomized trial.

Version: 4 Date: 23 December 2014

Reviewer: Silvia Burlina

Reviewer's report:

Major revisions:
1. There is confusion in the definition of sample size. In the abstract and in the manuscript (methods section) authors defined as primary outcome the differences in lipid levels (generally and not in particular LDL cholesterol) and in oxLDL. They statement that sample size was calculated to establish a difference in LDL cholesterol of 15%. Primary outcome must be clearly defined and should be the before-after difference in LDL cholesterol.
2. In methods section the authors do not describe any of the methodologies used to measure the parameters analyzed. However, it is essential to describe these methodologies, especially as regards the oxLDL, since this is one of the primary outcomes and there are many different assay kits to measure them.
3. Authors define the oxLDL as parameter of oxidative stress. This statement is not completely correct. OxLDL are in fact an indirect parameter of oxidation, the parameter of lipid peroxidation is represented by malondialdehyde.
4. In methods section, authors stated that they evaluated with questionnaires all the factors that can affect lipid levels and oxidative stress. No data about these questionnaire were shown. It is important, however, that these data are shown to attribute all the results only to therapy studied because it is well known that diet, for example, greatly influences both the levels of LDL cholesterol (up to 20%) and all the parameter of oxidative stress.

Minor revision:
1. In table 2 the unit of measurement of HbA1c must be changed from mg/dl to mmol/mol.
2. As regards secondary outcomes, it’s better to show in table or in the text all the value of CPK. Authors stated only that a mild CPK elevation was observed in all subjects.
3. As regards the analysis of the content of the capsules, authors should better specify the content of monacolin K and lovastatin separately.
4. authors should discussed the significant before-after differences in term of TG and apoB obtained in the intervention group.

Level of interest: An article of insufficient interest to warrant publication in a
scientific/medical journal

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

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests.