Reviewer's report

**Title:** Efficacy of tibolone and raloxifene for the maintenance of skeletal muscle strength, bone mineral density, balance, body composition, cognitive function, mood / depression, anxiety and quality of life / well-being in late postmenopausal women [greater than or equal to] 70 years: Study design of a randomized, double blind, double dummy, placebo-controlled, single-center trial

**Version:** 2 **Date:** 16 January 2008

**Reviewer:** Prathap Tharyan

**Reviewer's report:**

The protocol is well written and the design of the study is good but I have the following comments:

1. I did not find a trials registration number for this protocol.

2. The other concern I have is that since the Tibolone arm was stopped early, and since 57 women dropped out before 1 year, the data for the one year analysis (even assuming the ITT model) is likely to be unreliable and underpowered. Hence only the Ralofixene vs Placebo comparison will yield reliable results. This would affect the original hypothesis and may need to be specifically acknowledged.

Less critical:

3. The method of random sequence generation may need elaboration (CONSORT); it is generated by the pharmacy using 1:1:1 ratio but no further details are mentioned.

4. Blinding is not assessed (a CONSORT requirement) and I am unsure this is of importance; could outcome assessors or investigators guess from adverse effects of these drugs or other effects, the allocation. If they could, then observer rated outcomes such as GDS might be affected though BMD and other objective hard outcomes would not.