Reviewer’s report

**Title:** Rationale and design of the oral HEMe iron polypeptide Against Treatment with Oral Controlled Release Iron Tablets trial for the correction of anaemia in peritoneal dialysis patients (HEMATOCRIT trial).

**Version:** 2  **Date:** 26 June 2009

**Reviewer:** Giorgina Barbara Piccoli

**Reviewer’s report:**

In my opinion, There is no major compulsory revision needed. The concerns expressed in the following points should be considered as discretionary, but useful for the subsequent contextualization of the data.

This study protocol obtained ethical approval but was funded by a biotech company (Amgen Australia Ltd).

The background is clear and well documented. The hypotheses are clearly stated. The procedures are detailed.

As for the required questions:

1. Will the study design adequately test the hypothesis?
   Yes.

2. Are sufficient details provided to allow replication of the work or comparison with related analyses: if not, what is missing?
   Yes.

   My only concern regards the very low level of hemoglobin taken as a marker of adverse event (6.5 g/dL), albeit the specification that physicians may consider also a higher level associated with significant symptoms may allow earlier interventions. A list of the symptoms and a more detailed comment could help in replicating and comparing the results.

   A background information on the usual levels of Hemoglobin and ferritin in the Australian peritoneal dialysis population theoretically selectable for the study could also be of help, as such low hemoglobin levels are quite unusual in some other settings and as iron stores are a well known modulator of iron absorption.

3. Is the planned statistical analysis appropriate?
   Yes.

   The relatively low number of cases, however, doesn't allow stratifications for baseline data and potential confounders; therefore, the study is probably only a first step towards the definitions of tailored interventions.

4. Is the writing acceptable?
Yes, very clear

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**
I declare that I have no competing interests' below