Reviewer's report

Title: Rationale, Design and Methodology for a Double-Blind, Randomized, Placebo-Controlled Study of Escitalopram in Prevention of Depression in Acute Coronary Syndrome (DECARD)

Version: 1 Date: 19 November 2008

Reviewer: Prathap Tharyan

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1. Will the study design adequately test the hypothesis?

There is sufficient controversy about the utility of routine screening for depression after an acute coronary syndrome and efficacy of antidepressants in preventing cardiac outcomes to justify the trial (JAMA. 2008;300(18):2161-2171). The design is adequate to test whether this SSRI will prevent depression compared to placebo but may be underpowered for secondary outcomes

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

· The CT.gov registration documents has conflicting numbers of people likely to be randomised (266 and 240) and the manuscript lists 234. What is the actual number that will be/was enrolled?

· The registration document states randomization will occur 4 weeks after the coronary event while the manuscript states this will occur within 8 weeks.

· There are other less important discrepancies between inclusion and exclusion criteria of the two that would good to reconcile

· Allocation concealment is inadequately described as are other CONSORT elements pertaining to who recruits participants and if the outcome assessors are blinded and the methods that will be used to assess if blinded was adequate.

· The primary endpoint in the registration document are HDS and ICD diagnosis while in the manuscript, it is only the ICD diagnosis.

· The are many other psychiatric ratings planned other than the above and these do not figure in the outcomes at all either in the manuscript or in the registration document; this will lead to selective reporting bias, if they are mentioned as planned and not reported or reported only if significant The secondary analyses in the registration document is sketchy. A tertiary outcome is introduced in the manuscript that is not mentioned in the registration document.

· Deviations from protocol might be worth mentioning as the recruitment seems to have been completed.
3. Is the planned statistical analysis appropriate?
· Yes but may be underpowered to detect secondary outcomes.
4. Is the writing acceptable
· Grammatical errors need fixing throughout, though they are not many.