Reviewer’s report

Title: Oral flucloxacillin and phenoxyethymethylenicillin versus flucloxacillin alone for the Emergency Department outpatient treatment of cellulitis: study protocol for a randomised controlled trial

Version: 2 Date: 8 May 2013

Reviewer: Erik Cobo

Reviewer’s report:

Thank you very much for all the changes to the manuscript.

There is just a change (related to a major point: the main statistical analysis) that I would like you consider further.

In my previous review, I suggested:

“Please consider clarifying on page 15 line 2 the rule to combine the 2 population analyses (i.e., should both exclude the non-equivalence margin?).”

You have clarified adding a sentence that finishes with:

“As a result, both an ITT and per-protocol analysis will be performed on the resulting data to assess non-inferiority of the placebo/flucloxacillin combination.”

My suggestion was stronger, in the sense of clarifying the final decision rule. Instead of your sentence I was suggesting, for example:

“As a result, to declare non-inferiority of the placebo/flucloxacillin combination both ITT and per-protocol analysis should exclude the non-inferiority margin.”

This would probably be a convincing rule, but not the only one. I strongly recommend you to clarify this point—at least on the future blinded statistical analysis plan (page 10).