Reviewer's report

Title: Ofloxacin Plus Rifampicin Versus Doxycycline Plus Rifampicin In The Treatment Of Brucellosis. A Randomized Clinical Trial

Version: 4 Date: 17 February 2004

Reviewer: Leslie W Huson

Reviewer's report:

1) It is not appropriate to use statistical significance tests to compare baseline characteristics or to compare adverse event rates. The authors should therefore remove all p-values relating to such endpoints from Table 1 and from page 6 of the text. Adverse event rates should be reported using confidence intervals for the difference between rates on the two treatment arms.

2) It is not appropriate to compare post-treatment follow-up between the two treatment arms using a statistical significance test, since it is not clear that this is a clinical endpoint in the usual sense: the duration of follow-up may simply have been selected by clinicians on criteria other than those which might be affected by treatment. It is sufficient to report simply the means and standard deviations of the durations of follow-up.

3) The authors should provide an explanation of why 5 patients were not allocated to treatment as randomized, and why they were excluded from analysis. A conventional intent-to-treat analysis should have included such patients. However, in a very small study such as this, this is probably not necessary.

4) The authors should verify that the efficacy endpoints they used to compare the two treatment arms were specified in advance, in the study protocol. If this was not the case, they must justify the post-hoc selection of endpoints.