Reviewer's report

Title: Efficacy and safety of a two-step method of skin preparation for peripheral intravenous catheter insertion - a prospective multi-centre randomised trial

Version: 1  Date: 22 July 2006

Reviewer: Nigel Hall

Reviewer's report:

General

This manuscript describes a simple randomised controlled trial comparing two methods of skin preparation prior to PVC insertion. Outcome measures assessed are so-called 'pre-infection' signs - namely degree of thrombophlebitis following insertion. The authors should be congratulated for undertaking such a randomised multi-centre study. However the manuscript is long and at times confusing.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

The introduction is too long. It should be re-written to focus on the background to the study only. Matters of methodology (esp in ara 4) should be moved to the methods section. Paragraph 5 of the introduction should be removed. Reason for choosing degree of thrombophlebitis as the outcome measure should be included in the methods section and the discussion about the reason this was chosen should exist in the discussion. Specifically please justify the use of thrombophlebitis rather than bloodstream infection as an outcome measure. Although thrombophlebitis may be a cause of morbidity, it is unlikely to be life-threatening and the number of cases proceeding to bloodstream infection is low.

I do not understand the heading 'judgement criteria' on page 5

There is repetition relating to the two groups of patients (A and B) in the first paragraph of the Methods.

Please provide more information on the stopping of this study. Was there a planned interim analysis? If so at what stage was this planned, by whom was it performed and what were the stopping rules for this study. Economic reasons are cited - what were these? In my mind it is extremely poor science to discontinue a trial for economic reasons.

In the results section, please include data on number of patients eligible, those not enrolled and reasons for non-enrolment. Ideally conforming to the principles of the CONSORT statement.

With regard to the study stopping early because 'satisfactory' results were obtained, please provide further justification for this. It may be that had the study continued to its full recruitment, a difference in outcome measure between the two groups may have been observed.

A comparison of costs is mentioned in the conclusion which is not previous mentioned. Was cost examined as an outcome measure? If so how and what were the costs involved? If this is the case this should be mentioned and described fully in the methods section.

The last line of the conclusion is wrong. This study does NOT provide any such evidence that the two step procedure is better. There was no difference detected in this study!

The abstract should then be re-written to reflect the above conclusions

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Table 3 - it is unclear what the p-value refers to (one assumes is is A vs B but this is not clear)
Table 4 - again what does the p-value refer to and how was it calculated?

Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of limited interest

Quality of written English: Acceptable

Statistical review: No

Declaration of competing interests:
I declare I have no competing interests