Reviewer's report

Title: Standard abdominal wound edge protection with surgical dressings vs. coverage with a sterile circular polyethylene drape for prevention of surgical site infections. A patient and observer-blinded randomized controlled trial - BaFO

Version: 2 Date: 11 October 2011

Reviewer: Charlie Goldsmith

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The following issues are suggested to improve the protocol for the readers of Trials. The pages were numbered from 1 to 30.

1. P(age) 2, p(aragraph) 4, l(ine) 1. Add the date of registration and the date the first patient was randomized if that has happened.

2. P 3, l 2. Replace [Rational] by [Rationale].

3. P 3, p 1, l 3,5,6,10,11. Insert [,] rather than [.] to delimit each set of 3 digits.


6. P 3, p 2, l 14 and 15. Are these rates in the correct order?

7. P 3, p 2, l 19. Continue with the list and delete [etc.].

8. P 3, p 3, l 2. Since [or] logically includes [and], delete [and/]. Also P 6, p 4, l 4. Also P 7, p 2, l 1. Also P 8, p 3, l 7 and 9. Also P 10, p 5, l 1. Also P 11, p 5, l 6 and 7. Also P 13, p 2, l 5.

9. P 4, p 2, l 5. Did the study have a computed sample size justification and power analysis? Was this because of too little power?

10. P 4, p 2, l 8. Replace [parameters] by [variables]. A parameter is a characteristic of a distribution of a variable in a population and not the name for a variable in a sample.


12. P 4, p 3, l 3. Replace [Fig. 1] by [Figure 1] just as P 4, p 4, l 2 to be consistent.

13. P 4, p 3, l 5. Insert a space to read [meta analysis].

14. P 4, p 3, l 7. Should [folg] be [fold]? If so, on this and the previous line the relative risk should be stated and so should the comparison group. Fold is not a well defined term. The word increase is not needed, since values greater than 1
increase and those less than 1 decrease.

15. P 4, p 3, l 8. Suggest replacing [will] by [should]; presumably the results are not known!

16. P 4, p 5, l 1 lists [14 sites] and P 6, p 4, l 1 lists [15 centres]; which is correct? Are they all listed on P 15?

17. P 7, p 1, l 1 to 3. Are the envelopes individually numbered and will they be restricted to choosing one at a time?

18. P 7, p 3, l 2. Are the surgical dressings a standard list, if so which ones, and will they be recorded for each patient?


20. P 8, p 1. Will these locations provide equivalent temperatures, and will they be measured with the same instrumentation? This should be recorded as it might be a source of variation that matters.

21. P 8, p 2, l 2. [CRF] is not in the list of short forms on P 16.

22. P 8, p 2, l 9. How is it sent? Electronically and secure?

23. P 8, p 2, l 12. Insert a space to read [data management].

24. P 8, p 2, l 13 to 16 should be described in more detail and the programs documented.

25. P 8, p 3, l 3 to 5. These should be documented.

26. P 9, p 1, l 1. Delete [her/his] and [his] to remain gender neutral.

27. P 9, p 1, l 2. If copies of these are available they could be listed on the website as appendices.

28. P 9, p 3, l 4 and 5. Cite the R(eference) for these codes.

29. P 9, 4, l 1 and 2. Here you use [subject] and [patient]; should this not be consistently used in the entire paper?

30. P 9, p 4, l 3. Cite the website and the form; it could be included as an appendix to this paper.

31. P 9, p 4, l 6. Replace [significant] by [clinically important]. Who will make this determination? Are there any data on the reliability of this scoring?

32. P 9, p 4, l 11. [SAE] is not defined in the list on P 16.

33. P 9, p 5, l 3. Replace [proportion] by [percentage].

34. P 9, p 5, l 7. The Chi-Square does not seem to consider the stratification and blocking? Do you have software to do this? Cite the software.
35. P 10, p 1. Cite the method of the sample size calculation and the software used if relevant.

36. P 10, p 2. What will happen if fewer than 15 get recruited at any centre?

37. P 10, p 2 ff into P 11. This whole analysis section is on need of Rs to justify the procedures listed. The principles used to justify the sub-groups analyses should be cited. The software planned to be used should be cited. Also on P 11, it does not appear that the stratification and blocking have been considered in the analyses.

38. P 10, dash 4, l 2. [NNIS] is not defined in the list on P 16.

39. P 11, p 4, l 4. Until when?

40. P 11, p 6, l 8. Suggest replacing [perceived] by [conceived].

41. P 12, p 4. Provide Rs to these guidelines.

42. P 13, p 1, l 3. Replace [last decades] with dates.

43. P 13, p 1, l 9 and 10. Delete [In order] and capitalize [To] as the words are redundant in English. Also P 14, p 2, l 5 and 11.

44. P 13, p 2, l 1 to 4. Does the R on l 4 give data on all of these?

45. P 13, p 2, l 7 to end. Is there a R to document these issues?

46. P 14, p 1, l 2. Replace [,] by [. ] on both percentages.

47. P 14, p 1. Is power an issue with any of these trials?

48. P 14, p 2, l 1. Replace [is] by [are] since data is a plural word.

49. P 14, p 2, l 2. How are they blinded to the patch?

50. P 15, p 2. Where is [CS] in this list?

51. P 16 does not contain all the items in the footnote to Table 2. This list should be checked to make sure it is complete.

52. P 17. How big is the protector? Are there various sizes, and if so, how big are they. Will the size be recorded if they vary?

53. P 19, criterion 10 does not seem to be referenced anywhere.

54. P 20, footnote, l 4. Replace [optained] by [obtained].

55. P 21, second level, l(tem) 3B, l 2. Insert a space as [> 38]

56. P 21, last level, l 3A, l 1. The double dagger is not defined.

57. P 23 ff. These Rs apart from R 29 do not need a citation date.
A random sample of 10 Rs was checked for citation accuracy.

58. P 24 ff. Rs 13, 19, 20, 24, 27, 39, 40 and 41 appear to be correct. Congratulations.

59. P 24, R 21, l 3 should list [No 43] and provide the editors names. Which chapter is this?

60. P 26, R 38, l 3. Delete the periods to read [J Int Med Res].