1. Were both groups selected from the same source population?

- ☐ Yes
- ☐ No
- ☐ Yes, but method not described
- ☐ Not reported

2. Did both groups have the same risk of having the outcome of interest at baseline?

- ☐ Yes
- ☐ No
- ☐ Not reported
- ☐ Not applicable

3. Were subjects in both groups recruited over the same time period?

- ☐ Yes
- ☐ No
- ☐ Yes, but method not described
- ☐ Not reported
- ☐ Not applicable

4. Were measurement methods adequate and equally applied to both groups?

- ☐ Yes
- ☐ No
- ☐ Not reported

☐ Not applicable

5. Does the analysis control for baseline differences?

☐ Yes

☐ No

☐ Not applicable

6. Were important potential confounding and modifying variables taken into account in the design and analysis (i.e. through matching, stratification, or statistical adjustment)?

☐ Yes

☐ No

☐ Not applicable

7. Were the statistical methods used to assess the abstracted outcomes appropriate?

☐ Yes

☐ No

☐ Not applicable

8. Was the sample size sufficient to detect appropriate changes in the outcomes of interest? (i.e. was there an explanation of the statistical power?)

☐ Yes

☐ No

9. Was an attempt made to blind the outcome assessors?

☐ Yes

☐ No

☐ Yes, but method not described

☐ Not reported

☐ Not applicable

10. Was the time of follow-up equal in both groups?

☐ Yes

☐ No

☐ Not reported

☐ Not applicable

11. Overall attrition high (≥ 20%)?

☐ Yes (please state how high)

☐ No

12. Differential attrition high (≥ 15%)?

☐ Yes (please state difference)

- [ ] No
- [ ] Not applicable

13. Methods of adverse effects assessment

- [ ] Patient reported
- [ ] Physical exam at study visits
- [ ] Lab evaluations
- [ ] Standardized scale (e.g. WHO, UKU-SES)
- [ ] other (please specify)
- [ ] Not applicable

14. Adverse events pre-specified and defined?

- [ ] Yes
- [ ] No
- [ ] Not applicable

15. Ascertainment techniques for detecting adverse events non-biased and adequately described?

- [ ] Yes
- [ ] No
- [ ] Not applicable

16. Quality rating for observational study?

- [ ] Good
- [ ] Fair
- [ ] Poor - why?