Reviewer's report

Title: Efficacy and safety of a booster dose of influenza vaccination in solid organ transplant recipients: TRANSGRIPE 1-2, study protocol for a multicentre, randomized, controlled clinical trial.

Version: 3  Date: 23 April 2014

Reviewer: Graeme MacLennan

Reviewer's report:

This protocol describes the evaluation of a booster dose of flu vaccine compared to regular vaccination in solid organ transplant patients. I have only minor but essential revisions

Minor essential revisions

In the abstract the study is described as non-inferiority, but I think that this is a typo? Elsewhere the trial is referred to as non-commercial, perhaps that is what is meant here? The methods describe a superiority trial. If non-commercial is what is meant a better phrase may be "publicly funded"? What ever you decide the non-inferiority needs removed.

The standard of English requires slight improvement. For example the statistical analysis section is written in a mixture of past and future tense.

You may want to justify the decision to use LOCF for missing data given its known shortcomings in most situations.

Discretionary

I was unsure what the phrase "reference hospital" meant, but that could just mean that it is used outside of the UK to mean tertiary care? Perhaps "referral hospital" would be clearer.

There is a slight error in your sample size section, 462/0.9 is would 514 rounded up to even number to adjust for 10% drop-out but fortunately this has little impact on the sample size required.

Intention-to-treat and per-protocol should have hyphens.

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, and I have assessed the statistics in my report.
Declaration of competing interests:

I declare that I have no competing interests