Reviewer’s report

Title: Assessing the effectiveness and cost-effectiveness of subcutaneous nerve stimulation in patients with predominant back pain due to failed back surgery syndrome (SubQStim study): Study protocol for a multicentre randomized controlled trial.

Version: 1 Date: 17 April 2013

Reviewer: Allan Donner

Reviewer’s report:

This is a well done protocol which should be published after attention is given to the points below. The presence of a thorough systematic review is a great strength.

1. It is stated that "optimal medical management" will be defined by the investigator. Some description of what the individual components of such management are likely to consist of would be helpful to readers not directly familiar with treatment of back pain due to failed surgery syndrome.

2. Criteria are provided on page 8 as to what will define a "successful trial". This raises the question of how these criteria are to be interpreted in relation to the criterion that defines a successful primary outcome? That is, if the trial shows clinical and statistical significance with respect to the primary outcome, is this not sufficient for the trial to be considered a success? This needs clarification.

3. I understand that investigator and patient blindness is not feasible for this trial. But could the evaluation of the primary outcome be done blindly with respect to treatment group, eg by a qualified individual independent of the trial.

4. Please define "evaluable" patients.

5. A reference is needed to justify the use of a nominal 3% significance level at the end of the trial when preceded by two interim analyses. (Also in line 4 in the Sample Size and Power Calculations" section it should be specified that the 5% level referred to is 2-sided).

6. In connection with the proposed methods for handling missing data, what are "doubly robust estimators"?