Reviewer's report

**Title:** Impact of withholding early parenteral nutrition completing enteral nutrition in pediatric critically ill patients (PEPaNIC trial): study protocol for a randomized controlled trial

**Version:** 2  
**Date:** 5 March 2015

**Reviewer:** Merethe Kumle

**Reviewer's report:**

I do not have any competing interests in relation to this manuscript.

This study protocol for the ongoing RCT of enteral versus parenteral nutrition regimes for seriously ill children (PEPaNIC) addresses an important area in pediatric intensive care.

Today's recommendation in guidelines differs and is based on low level of evidence. The most updated systematic review I could find was Wong et al from 2014 including 9 studies, but only one RCT (identical with the RCT included in the Cochrane review by Joffe A et al from 2009).

Searching the WHO International Clinical Trials Registry Platform for corresponding ongoing or planned randomized clinical studies did not reveal other studies than PEPaNIC.

The RCT of early vs. late parenteral nutrition in critically adults, EPaNIC from 2011 and the ongoing RCT in critically ill children, PEPaNIC, are to a great extend identical. Greet Van den Berghe, Head of Dept Intensive Care Medicine, Katholieke Universiteit Leuven, has been a central person in both studies.

I have used SPIRIT statement (www.spirit-statement.org) and TIDieR checklist in conjunction with the TIDieR guide to evaluate the information in the manuscript. I have also read the protocol for the EPaNIC study published in Trials 2011 and the paper, appendix and
The protocol published in NEJM 20113 to search for more detailed information.

The aims of my evaluation were to determine:
1. Are sufficient details provided to allow replication of the work or comparison with related analyses: if not, what is missing?
2. Is the writing acceptable?

The protocol manuscript is well written and contains important but superficial information about the study design. I doubt that the protocol is detailed enough to allow replication or comparison with related analysis. To get enough information to replicate this study one has to contact Principal Investigator Greet Van den Berghe and ask for the complete protocol and questionnaires used. I would ask for additional information for items lacking essential information according to SPIRIT statement and TIDieR guide (attached document). I also assume that the research group has a detailed protocol equal to the protocol published in NEJM for EPaNIC in 20113.

To replicate PEPaNIC, I would also need original questionnaires and detailed information about clinical examinations and care in the PICU (in addition to information about data collection on page 9 and 17). This protocol, which I presume is a short version of the study protocol, is not detailed enough to make replication possible. But I have to say that the protocol is well written and make me curious about this study.

SPIRIT and TIDieR:
I have used (?) when information about the element is not reported/not sufficiently reported.

References


