Reviewer’s report

Title: The VICI-trial: High frequency oscillation versus conventional mechanical ventilation in newborns with congenital diaphragmatic hernia: An international multicenter randomized controlled trial

Version: 2 Date: 15 July 2011

Reviewer: Gerd Schmalisch

Reviewer’s report:

Despite significant advances in the treatment of CDH during the last years, CDH remains a rare but severe congenital anomaly with a high rate of mortality and morbidity. The optimal mechanical ventilation of such patients is controversially discussed and there is a lack of evidence-based ventilation strategies. A large randomized clinical trial is urgent necessary. High frequency oscillation ventilation (HFO) and conventional ventilation (CV) are currently widely used strategies. However some small studies have suggested that HFO may improve survival and pulmonary outcome in infants with CDH. The planed multicenter randomized controlled clinical trial in CDH infants aims to compare initial HFO and CV. This will provide in the future an optimization of ventilatory treatment strategies and a reduction of mortality and morbidity.

The planned study is well designed to test the hypothesis and the protocol is well written. The planned statistical analysis is appropriate.

Minor points

1. Please explain the abbreviation VICI.

2. The planned begin and the duration of the study is not specified.

3. There is no information about the used ventilators and ventilation modes. This was in the past an important problem of several HFO studies.

4. Laboratory parameters are sampled only in combination with routine measurements or if a catheter is already present. This can lead to essential drop outs which hamper the planned use of the ANOVA for repeated measurements.

5. LCI can not be measured by bodyplethysmography (page 11) and lung volumes measured by SF6 washout and bodyplethysmography are difficult to compare. One of the most interesting lung function parameter in CDH-infants is the respiratory compliance (see Roehr CC et al. J Pediatr Surg. 2009 44(7):1309-14).

6. Table 1: Explain the abbreviations (PMA, DC). Is there an intention to classify the BPD (mild, moderate, severe) according Table 1?

7. Is there an external funding of the study?

Level of interest: An article of importance in its field
Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests