Author's response to reviews

Title: Inhaled PGE1 in neonates with hypoxemic respiratory failure: Pilot randomized clinical trials to assess feasibility

Authors:

Beena Sood (bsood@med.wayne.edu)
Martin Keszler (mkeszler@wihri.org)
Meena Garg (mgarg@mednet.ucla.edu)
Jonathan M Klein (jonathan-klein@uiowa.edu)
Robin Ohls (rohls@salud.unm.edu)
Namasivayam Ambalavanan (nambalavanan@peds.uab.edu)
C. Micheal Cotton (cotte010@mc.duke.edu)
Monica Malian (mmalian@dmc.org)
Pablo Sanchez (Pablo.Sanchez@nationwidechildrens.org)
Satyan Lakshminrusimha (slakshmi@buffalo.edu)
Leif D Nelin (Leif.Nelin@nationwidechildrens.org)
Krisa P Van Muers (vanmeurs@stanford.edu)
Rebecca Bara (rbara@med.wayne.edu)
Shampa Saha (saha@rti.org)
Abhik Das (Adas@rti.org)
Dennis Wallace (dwallace@rti.org)
Rosemary D Higgins (higginsr@mail.nih.gov)
Seetha Shankaran (sshankar@med.wayne.edu)

Version: 2 Date: 20 May 2014

Author's response to reviews:

Dear Editors

We thank you for your comments; and have addressed each concern regarding the manuscript #1191582060129954, Inhaled PGE1 in neonates with hypoxemic respiratory failure: Pilot randomized clinical trials to assess feasibility.

1. Please move your ‘sources of support’ to the Acknowledgements section at the end of your paper.

The “source of support” has been moved to the acknowledgement section of the paper.

2. Please move your key words below your Abstract.

The “Key words” has been moved to follow the abstract.

3. Please include the dates of registration with your trial registration numbers at the end of the Abstract.

We have included the trial registration dates to the end of the abstract.

4. As your research involves humans please include a statement of ethical
approval in the Methods section of the manuscript, including the name of the body which gave approval, with a reference number where appropriate. Any experimental research on humans must be in compliance with the Helsinki Declaration. If your study is taking place in multiple sites please ensure you mention all of the ethical bodies that have approved the study at the different sites.

Lines 104 and 121 a statement of ethical approval has been added to the Methods section.

The following are the governing bodies for each site approved. Please note that although the site has IRB approval not all sites were issued an approval number.

* University of Alabama at Birmingham (IRB00000726)
* Women & Infants hospital (Brown University)
* University at Buffalo, State University of New York, Children & Youth IRB (IRB00004088)
* Parkland Health & Hospital System (University of Texas Southwestern) (IRB #092011-003)
* Duke University Health System IRB (IRB00009025)
* University of Iowa (IRB0000099)
* Nationwide Children's (FWA00002860)
* University of New Mexico Health Sciences Center
* University of Rochester (FWA 49386)
* University of California, Los Angeles, (FWA00004642 IRB00000172)
* Wayne State University (IRB082444MP2F)
* RTi IRB (FWA 3331)

5. Please include a statement in your Methods section explaining that you obtained informed consent from the parent of each participant.

Line 122: A statement of “informed parental consent obtained” was added

6. Please include a Conclusions section as the last section of the text. This should state clearly the main conclusions of the research and give a clear explanation of their importance and relevance. Summary illustrations may be included.

Line 353: A conclusion has been added.

Thank you

Beena Sood, MD