Author’s response to reviews

Title: Study protocol: Safety and Efficacy of Topiramate in Neonates With Hypoxic Ischemic Encephalopathy Treated With Hypothermia (NeoNATI)

Authors:

Luca Filippi (l.filippi@meyer.it)
Patrizio Fiorini (p.fiorini@meyer.it)
Marta Daniotti (marta.daniotti@gmail.com)
Serena Catarzi (s.catarzi@libero.it)
Sara Savelli (s.savelli@meyer.it)
Claudio Fonda (c.fonda@meyer.it)
Laura Bartalena (l.bartalena@ao-pisa.toscana.it)
Antonio Boldrini (a.boldrini@clp.med.unipi.it)
Matteo Giampietri (giamping@gmail.com)
Rosa Scaramuzzo (rosa.scaramuzzo@gmail.com)
Paola Papoff (p.papoff@libero.it)
Francesca Del Balzo (fdelbalzo@tiscali.it)
Alberto Spalice (a.spalice@tiscali.it)
Giancarlo la Marca (g.lamarca@meyer.it)
Sabrina Malvagia (s.malvagia@meyer.it)
Maria Luisa Della Bona (m.dellabona@meyer.it)
Gianpaolo Donzelli (donzelli@unifi.it)
Francesca Tinelli (francesca.tinelli@inpe.unipi.it)
Giovanni Cioni (gcioni@inpe.unipi.it)
Tiziana Pisano (t.pisano@meyer.it)
Melania Falchi (m.falchi@meyer.it)
Renzo Guerrini (r.guerrini@meyer.it)

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Author’s response to reviews: see over
To the Editor of

*BMC Pediatrics*

Florence, August 30, 2012

Dear Editor,

We are hereby submitting the revised version of the paper “Study protocol: Safety and Efficacy of Topiramate in Neonates With Hypoxic Ischemic Encephalopathy Treated With Hypothermia (NeoNATI)” by Luca Filippi et al., for possible publication as “Study protocol” in *BMC Pediatrics*.

In your letter, you reminded us that research involving human subjects must have been performed with the approval of an appropriate ethics committee, and that a statement to this effect must appear in the Methods section of the manuscript. In the previous version of the paper we specified that The study has been approved by the Ethics Committees of A. Meyer University Children’s Hospital, Florence, of University of Pisa and of La Sapienza University, Rome. In this version we added the number of protocol of the coordinator center and we upload a copy of this statement (in Italian).

In your letter you asked us if our study has received external funding. This study is a workpackage of the project “Drug treatment and neuroprotection in hypoxic-ischemic brain injury and neonatal-infantile seizures: 1) Pharmacokinetic and dose-finding study using a new tandem mass spectrometry micromethod; 2) Efficacy and tolerability profile; 3) Experimental in vitro and in vivo animal models” (principal investigator: Prof. Renzo Guerrini), that has been awarded a grant of 398.800 €, funded by Regional Health Research Program 2009 of Regione Toscana (decree n. 769 of 19/02/2010). We uploaded the declaration of Tuscany Region.

Thank you for your attention to our paper.

Yours sincerely,

Dr. Luca Filippi