

Author's response to reviews

Title: Establishing normal ranges for fetal electrocardiogram values for the healthy fetus of 18-22 weeks of gestation: a prospective cohort study

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Veldhoven, 4th of August 2016

Dear Editor,

Thank you for your response on our manuscript MS: 2066045883168059 entitled: “Normal ranges for fetal electrocardiogram values for the healthy fetus of 18-24 weeks of gestation: a prospective cohort study”.

1) Please explain why the title of the manuscript and that on the ethics document differ

The title of the document that was reviewed and approved by the medical ethical reviewing committee is: “Pilot study; The clinical evaluation of the non-invasive fetal electrocardiogram, regarding the diagnosis of congenital heart diseases”. This manuscript describes two distinct studies, that will be performed simultaneously. *Study 1* is the prospective cohort study that is described in this BMC manuscript, and is designed to determine the normal ranges for the fetal electrocardiogram values for the healthy fetus of 18-24 weeks of gestation. This study is carried out in Máxima Medical Centre and Diagnostiek voor U.

In *study 2*, fetuses that are diagnosed with congenital heart disease following the fetal anomaly ultrasound will be included. In this pilot study the fetal electrocardiogram values of these fetuses will be compared with the values that we found in *study 1*. Since this is a pilot study that is registered in the Dutch trial register (NL48535.015.14), we decided not to include this study in the BMC manuscript. This study is carried out in Máxima Medical Centre, Medical University Centre Sint Radboud (Nijmegen), Academic Medical Centre Amsterdam and Maastricht University Medical Centre.

Since the title of the medical ethical reviewing committee manuscript is not completely representing the content of *study 1*, we decided to rename the title in order to give a better description of *study 1*.

2) We understand that your study took place in Máxima Medical Centre as well as Diagnostiek voor U. However, it appears that we have only received documents for Máxima Medical Centre. Please ensure that the ethics approval document for Diagnostiek voor U is sent to us as soon as possible. The reason for this is because we need to ensure that the study has received ethics approval from all the sites involved in the study.

It is correct that measurement for *study 1*, as described in this BMC manuscript, were performed in both the Máxima Medical Centre and Diagnostiek voor U. This was approved as an amendment by our medical ethical reviewing committee. We will send the English version of this approval as email attachment to BMCSeriesEditorial@biomedcentral.com.

3) Please add a Declaration section to you paper with all the subheadings as detailed here: <http://bmcpregnancychildbirth.biomedcentral.com/submission-guidelines/preparing-your-manuscript/study-protocol>

A Declaration section with all requested subheadings is included in the manuscript (track changes, page 14, 15).

4) When uploading your paper to the system, please send in an attached copy of the manuscript, cover letter, and requested ethics approval documentation to the Editorial Office (BMCSeriesEditorial@biomedcentral.com)

We will upload our files to the system and will send them by email to the Editorial Office.

We hope that this additional information is sufficient in answering your questions and that the adjustments make this paper suitable for publication in BMC Pregnancy & Childbirth. We are looking forward to your decision.

Yours sincerely, on behalf of all the authors,

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