Fetal arrhythmia and long-term outcome

Published: 05-07-2006
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To estimate the cardiologic and neuropsychologic long term outcome in children born after fetal arrhythmia.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON30050

Source
ToetsingOnline

Brief title
Fetal arrhythmia

Condition

- Cardiac arrhythmias

Synonym
arrhythmia, heart rhythm disorder

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Arrhythmia, Fetal, Long term, Outcome

Outcome measures

Primary outcome

Mortality, cardiologic and neuropsychologic morbidity at the age of > 6 months.

Secondary outcome

None

Study description

Background summary

Fetal arrhythmia and long-term outcome

Background:
Fetal cardiac arrhythmia are detected in approximately 1% of all fetuses, most of these rhythm disturbances are the result of extrasystoles and are of little clinical significance. However, some types of arrhythmias are of clinical significance because they can cause fetal compromise, which may lead to the death of the affected fetus; persistent tachycardia and atrioventricular block are associated with fetal and postnatal mortality. Therefore these arrhythmia need immediate examination and if necessary therapy. Ultrasound examination is performed to exclude congenital heart defects and to differentiate the type of arrhythmia. Therapy can be induced preterm delivery or intrauterine treatment.

Study objective

To estimate the cardiologic and neuropsychologic long term outcome in children born after fetal arrhythmia.

Study design

Retrospective analysis:
In our ultrasound data-base all pregnancies were selected with the diagnosis fetal arrhythmia in the period january 1993 untill december 2005. From the data-base of the pediatric cardiology department we selected all neonates with fetal arrhythmia.

Follow-up:
First the referring physicians will be contacted to complete the short term follow-up. It concerns written information on the pregnancy, delivery and

puerperium. Then, the general physicians of the families will be notified, on paper and by telephone. If there are no contraindications, the families will be contacted by letter and by telephone. The families will be asked to participate in the study. It involves a standard pediatric cardiologic examination and ECG by a child cardiologist and a neuropsychologic test. The child will not undergo invasive tests. Every examination will take plusminus 60 minutes. With anamnesis of the parents and the child we want to examine the neurologic and cardiologic condition of the child. In case of abnormalities detected by the examination, the familiy physician will be notified and it will be discussed with the parents. The responsibility for the neuropsychologic test is with dr J. Feenstra (psychologist) and for responsible for the pediatric cardiologic examination is dr N.A. Blom (child cardiologist).

Study burden and risks

According to the examiners there is little to no burden or risk for the children who are being examined.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Fetal arrhythmia

Exclusion criteria

-

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL12047.058.06