Fetal Atrial Flutter & Supraventricular Tachycardia (FAST) Therapy Trial

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The FAST Therapy Trial is a prospective trial of patients with a new diagnosis of fetal SVA aimed to compare the impact of different perinatal treatment strategies from the time of SVA diagnosis to birth or death1) The primary outcome will be the...

Ethical review	Approved WMO
Status	Completed
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON47515

Source
ToetsingOnline

Brief title
FAST Therapy Trial

Condition

- Cardiac arrhythmias
- Foetal complications

Synonym
Fetal Arrhythmias, rhythm disturbance of the unborn child

Research involving
Human

Sponsors and support

Primary sponsor: Hospital for Sick Children
Source(s) of monetary or material Support: Canadian Institutes of Health Research (CIHR)

Intervention

Keyword: AF (Atrial Flutter), antiarrhythmic medication, Fetal Tachycardia, SVT (Supraventricular Tachycardia)

Outcome measures

Primary outcome

Term delivery (at least 37 weeks) with a normal cardiac rhythm.

Secondary outcome

*Proportion of patients with cardioversion over time.

* Proportion of patients with treatment failure:

- Fetal demise

- Cross-over to 2nd and/or 3rd line therapy

- Progression to fetal hydrops (SVT or AF/no hydrops)

- Recurrence of SVA on maintenance therapy

- Delivery without SVA termination

*Proportion, timing and cause of death prior to 1 month corrected age.

*Proportion of other events: periventricular leucomalacia and bleeds; NEC;

respiratory distress.

*Average gestational age at birth and birth weight z-scores.

*Average days of maternal and neonatal hospitalization related to SVA therapy.

*Maternal prevalence of pregnancy/treatment-related AEs (including caesarean

section)

Study description

Background summary

Pregnancies can be complicated by an abnormally fast heart rate up to 300 beats per minute due to supraventricular tachyarrhythmia (SVA) in the unborn baby (fetus). This carries significant risks because the baby can tolerate fast heart rates for only a short period before heart failure, shock or even death occurs. Premature delivery and perinatal death are frequent adverse outcomes of babies with heart failure and uncontrolled SVA before birth. Treatment is offered to most mothers to normalize the fetal heart rate to prevent or treat fetal heart failure and to continue the pregnancy to term with a normal delivery. The FAST Therapy Trial aims to determine the efficacy and safety of standard drug therapy regimens for fetal SVA.

Study objective

The FAST Therapy Trial is a prospective trial of patients with a new diagnosis of fetal SVA aimed to compare the impact of different perinatal treatment strategies from the time of SVA diagnosis to birth or death
1) The primary outcome will be the proportion of a term delivery of a live-born child with a normal cardiac rhythm
2) Secondary outcomes will determine the efficacy of 1st line, 2nd line, and maintenance drug therapy in controlling the different arrhythmias prior to birth and patient safety

Study design

This study is an open label Randomized Clinical Trial which compares standard drug therapies.
Furthermore, there is a Prospective Registry in which patients who are not randomized for the RCT's, but who have the diagnosis SVA, can be included. In this line of the trial, patients can be included who do not receive medical treatment, or who do get therapy but are not eligible for the RCTs within the FAST therapy trial.

Daarnaast is er een Prospectieve Registry waarin niet gerandomiseerde patiënten met de diagnose SVA kunnen worden geïncludeerd. In deze tak van de studie kunnen patiënten worden geïncludeerd die geen therapie krijgen, of die wel therapie krijgen, maar niet voldoen aan de inclusiecriteria voor de RCT's binnen de FAST trial.

Intervention

A randomisation of standard medicine protocols are used to treat the AF and SVT.

Study burden and risks

No extra risk. Additional to the standard medical treatment a questionnaire of about 5 minutes is completed. .

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Diagnosis: Fetal AF without hydrops or SVT without hydrops or SVT with hydrops.
* Tachyarrhythmia significant enough to justify immediate transplacental pharmacological treatment.
Maternal conditions:
* Gestational age <36 0/7 weeks at time of enrolment.
* Untreated at time of enrolment.
* Singleton pregnancy.
* Healthy mother with normal pre-treatment cardiovascular findings.

* Mother capable to make her own health decisions and to understand and follow medical instruction.

Exclusion criteria

* Fetal AF with hydrops.
* Any maternal-fetal conditions associated with high odds of premature delivery and/or death.
Maternal conditions:
* Any relevant preexisting heart condition.
* Relevant preexisting obstructive airway disease including asthma.
* History of chronic substance abuse.
* Intake of QT-prolonging medication.
* Serum potassium level <3.3 mEq/L.
* Ionized serum calcium level of <1 mmol/l.
* Serum creatinine level >1.1mg/dl.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	31-01-2020
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Flecaïnide
Generic name:	Flecaïnide

Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Lanoxin
Generic name:	Digoxin
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Sotalol
Generic name:	Sotalol
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	15-03-2018
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	24-01-2019
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EudraCT	EUCTR2015-005743-14-NL
ClinicalTrials.gov	NCT02624765
CCMO	NL56803.000.17

Study results

Date completed:	31-03-2024
Results posted:	06-07-2021
Actual enrolment:	13

First publication
01-01-1900