Trial Description

Title

Fetal Atrial Flutter & Supraventricular Tachycardia (FAST) Therapy Trial

Trial Acronym

FAST

URL of the trial

http://FastTherapyTrial.com

Brief Summary in Lay Language

The purpose of this study is to compare the results of two commonly used treatments for unborn babies with atrial flutter or with supraventricular tachycardia. The medications digoxin, sotalol or flecainide are used alone or in combination to treat these two conditions. If hydrops is present treatment is started with two medications to improve the chances of successful treatment.

Brief Summary in Scientific Language

Three prospective RCT sub-studies to determine the efficacy and safety of specific transplacental drug regimens in suppressing fetal AF without hydrops, SVT without hydrops, and SVT with hydrops.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00016915**
- Date of Registration in DRKS: **2019/04/17**
- Date of Registration in Partner Registry or other Primary Registry: **2015/12/18**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **265/18-AMG-ff-monozentrisch , Ethik-Kommission der Medizinischen Fakultät der Rheinischen Friedrich-Wilhelms-Universität**

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Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2015-005743-14**
- Primary Registry-ID: **NCT02624765 (ClinicalTrials.gov)**

Health condition or Problem studied

- Free text: **fetal atrial flutter, fetal supraventricular tachycardia, fetal hydrops**
- ICD10: **I48 - Atrial fibrillation and flutter**
- ICD10: **I47 - Paroxysmal tachycardia**

Interventions/Observational Groups

- Arm 1: **RCT A - AF WITHOUT HYDROPS: DIGOXIN vs. SOTALOL**
  ARM 1: DIGOXIN:
  Aim: therapeutic maternal trough level of 1.0-2.0 ng/ml
  ARM 2: SOTALOL:
  oral Sotalol 80 mg TID or 120 mg BID (240 mg/day)

- Arm 2: **RCT B - SVT WITHOUT HYDROPS: DIGOXIN vs. FLECAINIDE.**
  ARM 1: DIGOXIN:
  Aim: therapeutic maternal trough level of 1.0-2.0 ng/ml
  ARM 2: FLECAINIDE:
  Aim (if available): therapeutic maternal drug level of 0.2-1 µg/ml
  Oral 100 mg TID (300 mg/day)

- Arm 3: **RCT C - SVT WITH HYDROPS: DIGOXIN PLUS FLECAINIDE vs. DIGOXIN PLUS SOTALOL.**
  ARM 1 DIGOXIN plus FLECAINIDE
  DIGOXIN:
  Aim: therapeutic maternal trough level of 1.5-2.0 ng/ml. oral Flecainide 100 mg TID (300 mg/day)
  ARM 2: DIGOXIN PLUS SOTALOL:
  DIGOXIN
  Aim: therapeutic maternal trough level of 1.5-2.0 ng/ml. oral Sotalol 160 mg

BID (320 mg/day)

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **Yes**

Primary Outcome

proportion of term deliveries of live-born children with a normal cardiac rhythm. Term delivery is defined as birth 37 0/7 weeks gestation or later

Secondary Outcome

•Proportion of participants with cardioversion over time.
•Proportion of participants with treatment failure:
oNumber of participants with treatment failure compared to number of participants with successful treatment. Treatment failure is defined as one of the following:
- cross-over to another drug
- SVT/AF that persists to birth
- preterm birth
- death
•Cause of death (prenatal, postnatal) Proportion of participants (infants) with arrhythmia related death
•Average gestational age at birth
•Birth weight (z-scores)
•Average days of maternal and neonatal hospitalization related to SVA therapy
•Maternal prevalence of pregnancy/treatment-related AEs and outcomes
Proportion of AEs / adverse outcomes (prenatal, postnatal)

Countries of recruitment

- DE **Germany**
- UK **United Kingdom**
- US **United States**

US **United States**

- AU **Australia**
- NL **Netherlands**
- CA **Canada**

Locations of Recruitment

- University Medical Center **Priv. Doz. Dr. med. Ulrike Herberg,Universitätsklinikum Bonn, Zentrum für Kinderheilkunde Abteilung für Kinderkardiologie Adenauerallee 119 53113 Bonn, Bonn**
- Medical Center **Dr. Darren Hutchinson, The Royal Women's Hospital, Melbourne, Melbourne**
- Medical Center **Dr. Edgar Jaeggi, The Hospital for Sick Children, Toronto , Toronto**
- Medical Center **Dr. Greg Ryan, Mount Sinai Hospital, Toronto , Toronto**
- Medical Center **Dr. Lisa Hornberger, University of Alberta, Western Children's Heart Network, Edmonton , Edmonton**
- Medical Center **Dr. Julene Carvalho, St George's University Hospital Foundation Trust London, London , London**
- Medical Center **Dr. Janet Brennand, The Ian Donald Centre for Foetal Medicine, Southern General Hospital, Glasgow , Glasgow**
- Medical Center <style fontName='DejaVu Sans' isBold='true'>Dr. Margarita Bartsota, Chelsea & Westminster Hospital NHS Foundation Trust, London , London</style>
- Medical Center **Dr. Phil Saul, West Virginia University, Morgantown, WV , Morgantown**
- Medical Center **Dr. Shaine Morris, Baylor College of Medicine, Houston, TX , Houston**
- Medical Center **Dr. Anita Moon-Grady, University of California San Francisco, San Francisco, CA , San Francisco**
- Medical Center **Dr. Allison Divanovic, Cincinnati Children"s Hospital Medical Centre, Cincinnati , Cincinnati**
- Medical Center **Dr. Erika Peterson, Children's Hospital of Wisconsin, Milwaukee , Milwaukee**
- Medical Center **Dr. Bettina Cuneo, Children's Hospital Colorado, Aurora, CO , Aurora**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/01/29**
- Target Sample Size: **600**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

•Mother has provided written informed consent to participate in the RCT
•Mother aged ≥18 years at time of enrolment
•Fetal AF without hydrops (RCT A) or SVT without hydrops (RCT B) or SVT with hydrops (RCT C)
•Tachyarrhythmia that is significant enough to justify immediate transplacental pharmacological treatment:
- Tachycardia ≥ 170 bpm during +100% of time (≤ 30 0/7 weeks of gestation)
- Tachycardia ≥ 180 bpm during at least 10% of observation time
- Tachycardia ≥ 280 bpm
- Tachycardia with fetal hydrops
•Gestational age ≥ 12 0/7 weeks and <36 0/7 weeks at time of enrolment
•Untreated arrhythmia at time of enrolment
•Singleton Pregnancy
•Healthy mother with ± normal pre-treatment cardiovascular findings:
- ECG within normal range (sinus rhythm; QTc ≤ 0.47; PR ≤ 0.2 sec; QRS: ≤ 0.12 sec; insignificant anomalies isolated premature beats; isolated complete right bundle branch block;non-specific ST-T segment changes allowed)
- Maternal resting heart rate ≥ 50 bpm
- Maternal Systolic BP ≥ 85 mm Hg

Exclusion criteria

•Fetal AF with hydrops (condition is too infrequent to be studied in a separate RCT sub-study; eligible for Registry)
•Any maternal-fetal conditions associated with high odds of premature delivery and/or death other than tachycardia (e.g. severe IUGR; premature rupture of membrane; life-threatening maternal disease (incl. pre-eclampsia; HELLP syndrome); severe congenital fetal abnormalities (T 13 or 18; surgery or death expected < 1 month))
•History of significant maternal heart condition (open heart surgery; sick sinus syndrome; channelopathy (long QT, Brugada syndrome); ventricular tachycardia; WPW syndrome; high-degree heart block; cardiomyopathy)
•History of significant maternal obstructive airway disease including asthma
•Maternal serum potassium level < 3.3mmol/L / <3.3 mEq/L
•Maternal ionized serum calcium level of <1 mmol/L / <4mg/dL or total serum calcium level <2mmol/L / < 8mg/dL
•Maternal serum creatinine level > 97.2 µmol/L (>1.1 mg/dl)
•Maternal intake of QT-prolonging medication including but not limited to the following medications:
http://www.crediblemeds.org/pdftemp/pdf/CompositeList.pdf

Addresses

- **Primary Sponsor**

  The Hospital for Sick Children
  Mr. Dr. Edgar Jaeggi
  M5G 1X8 Toronto
  Canada

  Telephone: **+1-416-813-7654 ext. 309423**
  Fax: **[---]***
  E-mail: **FAST.Trial at sickkids.ca**
  URL: **https://www.fasttherapytrial.com/study-sponsor**

- **Contact for Scientific Queries**

  Universitätsklinikum BonnRheinische Friedrich - Wilhelm - UniversitätZentrum für KinderheilkundeAbteilung für Kinderkardiologie
  Ms. PD Dr. med. Ulrike Herberg
  Sigmund-Freud-Str. 25
  53127 Bonn
  Germany

  Telephone: **+49-228-287-33350**
  Fax: **+49-228-287-33360**
  E-mail: **Ulrike.Herberg at ukbonn.de**
  URL: **www.ukb.uni-bonn.de**

- **Contact for Public Queries**

  Universitätsklinikum BonnRheinische Friedrich - Wilhelm - UniversitätZentrum für KinderheilkundeAbteilung für Kinderkardiologie
  Ms. PD Dr. med. Ulrike Herberg
  Sigmund-Freud-Str. 25
  53129 Bonn
  Germany

  Telephone: **+49-228-287-33350**
  Fax: **+49-228-287-33360**
  E-mail: **Ulrike.Herberg at ukbonn.de**
  URL: **www.ukb.uni-bonn.de**

Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

  Canadian Institute of Health Research (CIHR)

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Canadian Institute of Health Research (CIHR)
160 Elgin Street
K1A 0W9 Ottawa
Canada

Telephone: **[---]***
Fax: **[---]***
E-mail: **support at cihr-irsc.gc.ca**
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*