Influence of menarche and menstrual cycle on QTc interval in girls with genotype positive LQT1 and LQT2

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Evaluate the effect of menarche and menstrual cycle on the QTc interval among girls with genetically-confirmed mutations causing LQTS type 1 (LQT1) and type 2 (LQT2).

Ethical review	Not approved
Status	Will not start
Health condition type	Cardiac and vascular disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON40681

Source ToetsingOnline

Brief title Influence of menarche and menstrual cycle in congenital LQTS

Condition

• Cardiac and vascular disorders congenital

Synonym Congenital long QT syndrome, LQTS

Research involving Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum **Source(s) of monetary or material Support:** Afdeling Kindercardiologie

Intervention

Keyword: Congenital, LQTS, Menarche, Menstrual Cycle

Outcome measures

Primary outcome

The QTc interval will be measured pre- and post-menarche and during 3 phases of

the menstrual cycle. In boys QTc interval will be measured at approximately

the same time intervals as the girls during their menstrual cycle.

Secondary outcome

Not applicable

Study description

Background summary

The congenital long QT syndrome (LQTS) is an inherited disorder defined by the prolongation of the QT interval on electrocardiogram (ECG). If untreated, polymorphic ventricular tachycardia (torsade des pointes) may occur, leading to syncope or even sudden death. Normal cardiac repolarization adapts to heart rate, so a standardized heart rate correction formula is used to correct the QT interval for heart rate (QTc) allowing the comparison of the QT intervals at different heart rates. The QTc interval varies with age and gender in patients with LQTS, depending on the differ genotypes. These changes are associated with differences in the clinical course of the disease. It hadsbeen proposed that sex hormones may play a role in the complex relationship between genotype, age, gender and QTc interval.

Hence, studies have been performed to examine the influences of pregnancy and menopause in women with LQTS. Currently, however, there is no data regarding the influence of menarche and menstruation cycle in these patients.

Study objective

Evaluate the effect of menarche and menstrual cycle on the QTc interval among girls with genetically-confirmed mutations causing LQTS type 1 (LQT1) and type 2 (LQT2).

Study design

The study consists of both a retrospective- and a prospective observational design.

Study burden and risks

In all patients three ECGs will be obtained. Girls not using oral contraceptive therapy will be asked to use a urinary ovulation predictor and to measure daily basal body temperatureto identify ovulation. They will document this daily in a study dairy This study does not provide an advantage for the participating patient. However, acquiring more information about hormonal influences on QTc interval will give more insight into the clinical course of LQTS and may be helpful in risk-stratification and the further management of these same patients in the future.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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Adolescents (12-15 years) Adolescents (16-17 years) Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

All girls and boys born between January 1st 1985 and December 31st 2001, who are diagnosed based on their genotype with LQT1 or LQT2 and seen in the Academic Medical Centre in Amsterdam between January 1st 2003 and December 31st 2013, will be included in the study population.

Exclusion criteria

- Premenarcheal

- Pregnancy

- Use of hormonal contraceptive therapy other than combined estrogen-progestin oral contraceptives (i.e. intrauterine contraception, contraceptive vaginal ring, etonogestrel contraceptive implant, injectable contraceptives or progestin pills)

- Double mutation carriers or compound heterozygote
- Body mass index (BMI) for age greater than the 95th percentile
- History of polycystic ovary syndrome (PCOS)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other
Recruitment	

NL Recruitment status: Will not start Enrollment: 0

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Type:

Anticipated

Ethics review

Not approvedDate:25-11-2014Application type:First submissionReview commission:METC Amsterdam UMC

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 CCMO ID NL49238.018.14