Influence of the Menstrual Cycle on the QT interval in females with Long QT-syndrome

Published: 27-05-2021
Last updated: 08-04-2024

Evaluate the effect of the menstrual cycle on QTc among females with LQT1 or LQT2 and to put our previous findings in a broader perspective by including controls groups and older females.

Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON54957

Source
ToetsingOnline

Brief title
Menstrual cycle in LQTS

Condition

- Cardiac arrhythmias
- Cardiac and vascular disorders congenital

Synonym
long QT syndrome, LQTS

Research involving
Human

Sponsors and support

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

Intervention

Keyword: LQTS, menstrual cycle, QT interval

Outcome measures

Primary outcome

Concomitant estradiol and pregnanediol fluctuations will be obtained together with the QTc at three time points during the menstrual cycle or approximately corresponding with the phases of the menstrual cycle in LQTS-females with and without HCT, respectively.

Secondary outcome

Daily QTc fluctuations during 1 month in men and women both with and without HCT.

Study description

Background summary

Congenital long QT syndrome (LQTS) is a potentially lethal inherited disorder defined by prolongation of the QT-interval corrected for heart rate (QTc) on the electrocardiogram (ECG). If untreated, polymorphic ventricular tachycardia (Torsades de Pointes, TdP) may occur, leading to syncope or sudden death. Children and adolescents constitute an especially important risk group. The QTc varies with age and sex in patients with LQTS, depending on the different genotypes. These changes are associated with differences in the clinical course of the disease. It has been proposed that sex hormones may play an important role in the complex relationship between genotype, age, sex and QTc. Hence, studies have been performed to examine the influences of pregnancy and menopause in women with LQTS. Recently, we have assessed the effect of the menstrual cycle on the QTc in twenty LQTS type 1 (LQT1) and type 2 (LQT2) females between the age of 12-21 years. We found that the QTc was longer in LQT2-females during the luteal-phase and that pregnanediol levels were associated with significant changes in heart rate and QTc during a resting supine position. Furthermore, we found a decreased QT-interval/QTc adaptation after standing during the ovulation-phase but not the luteal-phase, especially in LQT2-girls. To put these findings in a broader perspective, we want to

expand our protocol as suggested earlier (METC 2014_159 and METC2015_186).

Study objective

Evaluate the effect of the menstrual cycle on QTc among females with LQT1 or LQT2 and to put our previous findings in a broader perspective by including controls groups and older females.

Study design

This study will be a prospective observational study.

Study burden and risks

As only extra ECG recordings and urinary samples of hormone levels are being conducted, the risk of this study is expected to be low. The burden for LQTS females will consist of 3 visits with ECG recordings and collection of urinary samples with a total duration of ~30 minutes. LQTS-females without HCT will be asked to identify ovulation using urinary ovulation predictors. Furthermore, LQTS males and females will be requested to record an self-recorded ECGs three times a day for the period of approximately 4 weeks. The recording of these ECGs and the sending of them to the investigator takes up 1-2 minutes per day. This study does not have an advantage for the participating patients. However, all ECG recordings will be analysed by the investigator and shared with the treating physician for use to optimize individual risk stratification in regular care, which might have an advantage for the participants. Furthermore, acquiring more insight in the role of the menstrual cycle may improve risk stratification for life-threatening arrhythmias for all LQTS-patients.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Genetically confirmed LQT1 or LQT2
Age between 12 and 30 years

Exclusion criteria

Pregnancy and post-partum period until the end of breastfeeding
The use of hormonal contraceptive therapy other than combined oestrogen-progestin oral contraceptives (i.e. intrauterine contraception, contraceptive vaginal ring, etonogestrel contraceptive implant, injectable contraceptives or progestin pills)
History of anorexia nervosa or polycystic ovary syndromeHistory of anorexia nervosa or PCOS
BMI for age greater or less than the 99th percentile
Double mutation carrier or compound heterozygote
Mutations of unknown pathogenicity

Study design

Design

Study type:	Observational non invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2021
Enrollment:	0
Type:	Anticipated

Ethics review

Approved WMO

Date:	27-05-2021
Application type:	First submission
Review 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	ID
CCMO	NL75145.018.20