MIBG scintigraphy in patients with inherited monogenic electric heart diseases

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The main objective of the study is to establish whether cardiac MIBG scintigraphy can be used as a risk-stratification tool in LQTS, Brs and CPVT.

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

Summary

ID

NL-OMON31577

Source
ToetsingOnline

Brief title
MIBG scintigraphy in inherited monogenic electric heart diseases

Condition

- Cardiac arrhythmias

Synonym
heart rhythm disorders, ventricular fibrillation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Brugada syndrome, CPVT, Long QT syndrome, MIBG

Outcome measures

Primary outcome

Differences between symptomatic and asymptomatic patients within a group with

regards to the proportion of patients with abnormal MIBG scintigram.

Secondary outcome

not applicable

Study description

Background summary

The clinical heterogeneity within families with the Long QT syndrome (LQTS), Brugada syndrome (Brs) and cathecholaminergic polymorphic ventricular tachycardia (CPVT) can be enormous, varying from asymptomatic family-members to family members who experience multiple syncope*s and die ultimately at a young age due to ventricular fibrillation. Risk-stratification in these patients is difficult, as there are no risk-stratification tools available. Dysfunction of the cardiac pre-synaptic activity appears to play an important role in the symptomatic patients. Therefore, we hypothesize that cardiac MIBG scintigraphy (a tool to asses the cardiac sympathetic pre-synaptic function) is an effective risk stratification tool in these patients.

Study objective

The main objective of the study is to establish whether cardiac MIBG scintigraphy can be used as a risk-stratification tool in LQTS, Brs and CPVT.

Study design

Observational study in which a single cardiac MIBG scintigram is made. This scintigram will be related to disease severity.

Study burden and risks

MIBG scintigraphy is a diagnostic test, using a radiopharmacon, which is safely used in routine clinical practice for various conditions, including cardiac disease (but not for the conditions described in this application). Because the method used in this study is identical to the methods used in established routine clinical tests, we anticipate that the risks of this study are equally small as in these routine clinical tests. The extra burden for all patients is a single injection of the radiopharmacon. The patients require a hospital visit for scintigraphy.

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

mutations carriers of the following diseases:
Long QT syndrome

Brugada syndrome
CPVT

Exclusion criteria

pregnancy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2008
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO

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	NL21342.018.07