The Development of Patient-Specific Cardiomyocytes Differentiated from Induced Pluripotent Stem Cells as a model for the Molecular, Cellular, and Electrophysiological Characterization of Inherited Cardiac Arrhythmias

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

Summary

ID

NL-OMON32488

Source
ToetsingOnline

Brief title
iPS Cell model for Inherited Cardiac Arrhythmias

Condition

- Cardiac arrhythmias
- Cardiac and vascular disorders congenital

Synonym
heart rhythm disorders, inherited arrhythmias

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: NWO,NHS;Duke

Intervention

Keyword: Cell model, Induced pluripotent stem cells, Inherited Arrhythmias

Outcome measures

Primary outcome

: Cellular, molecular and electrophysiological characterization of the

iPS-CM.

Secondary outcome

n.v.t.

Study description

Background summary

Inherited arrhythmias are a known cause of sudden cardiac death and are responsible for significant mortality and morbidity in developed nations. In recent years, the discovery of pathogenic mutations in inherited arrhythmia syndromes has provided novel insights for the understanding and treatment of diseases predisposing to sudden cardiac death. Nevertheless there are still a lot of questions to answer. The current models used are not competent to answer all the questions, as they are not capable to accurately show the molecular cardiac specific phenotype of the mutation. Recently it became possible to reprogram somatic cells to an embryonic like state, induced pluripotent stem cells (iPS). The techniques to differentiated stem cells to cardiac myocytes was already available. Now it is possible to create patient- and therefore mutation-specific human cardiac myocytes to study inherited arrhythmias

Study objective

With iPS-CM we want to elucidate the effect of mutations on cellular and

molecular level. With this knowledge it will be possible to understand the mechanism underlying heterogeneity in various arrhythmia syndromes, which will open the door for developing specific therapies.

Study design

We want to create a BioDataBank with HDF. When possible the HDF will be collected from patients during surgery for routine clinical indications. When no surgery is planned a Stansbiopsy of skin will be performed. These HDF cells are used to create iPS-CM.

Study burden and risks

When possible skin biopsies at the incision site will be collected from patients at the time of surgery routine clinical indications. This should pose no additional risk to the patient. When no surgery is planned a Stansbiopsy of skin will be performed, this causes in practice no significant pain nor scarring, no suturing is needed. There is no personal benefit to participate in this study.

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

Adult patients diagnosed with inherited arrhythmias.

Exclusion criteria

The inclusion criteria includes only the study population. Since there is minimal burden on patients, there is no reason why someone in this group can not participate in this study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2009
Enrollment:	600
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	NL30225.018.09