Heart failure and cardiac repair; genes for heart repair and plasticity

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- Identify key factors of the cardiac transcriptome in patients with cardiac malformations- Identify the transcriptional regulatory interactions underlying the cardiac transcriptome- Bioinformatically map and analyse the cardiac regulatory network...

Ethical review	Approved WMO
Status	Pending
Health condition type	Congenital cardiac disorders
Study type	Observational invasive

Summary

ID

NL-OMON30384

Source
ToetsingOnline

Brief title
Heart failure and cardiac repair; genes for heart repair and plasticity

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: cardiac formation, congenital heart defect, genes, underdeveloped heart chamber

Outcome measures

Primary outcome

genetic profile

Secondary outcome

not applicable

Study description

Background summary

Knowledge about the mechanisms in heart development is important for improving therapy in cardiac disease. Nature provides us with two model systems, that of the normal development path and that of the abnormal or incorrect pathway which leads to congenital heart defects.

Study objective

- Identify key factors of the cardiac transcriptome in patients with cardiac malformations
- Identify the transcriptional regulatory interactions underlying the cardiac transcriptome
- Bioinformatically map and analyse the cardiac regulatory network to show the potential impact of key regulators and targets on the development of cardiac malformations

Study design

Identify patients with underdeveloped heart chamber in the CONCOR-database for DNA-analysis. For analysis we also need to compare the already available DNA of the patient in the CONCOR-bank with the DNA of his parents. If we find a mutation in the patient then by comparison with the parent's DNA we know if it concerns either a new mutation or a polymorphism.
Patients are approached via their own cardiologist to approach their parents for study participation. After informed consent parent's DNA will be isolated from blood and genetic analysis will be done.

Study burden and risks

-Patients with the specified congenital heart defects are asked to contact

their parents for DNA-research.
-The risks for the parents are minimal, comparable with any other vena punction.
-All data will be anonymised in a coded database.

Contacts

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NL
Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

parent of child with an underdeveloped heart chamber

Exclusion criteria

not applicable

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):	01-04-2006
Enrollment:	1000
Type:	Anticipated

Medical products/devices used

Registration:	No

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	NL11167.018.06