European registry for ICD and CRT devices in pediatrics and adults with congenital heart disease (Euripides registry)

Published: 16-03-2009
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European registry of children and patients with congenital heart disease that undergo ICD or CRT implantation. This will lead to a larger amount of data leading to increased knowledge about long-term consequences and potential complications.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital cardiac disorders
Study type	Observational non invasive

Summary

ID

NL-OMON32025

Source
ToetsingOnline

Brief title
Registration of ICD and CRT devices

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital

Synonym
rhythm disturbance'; syncope

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cardiac Resynchronization Therapy, Congenital Heart Disease, Internal Cardiac Defibrillator

Outcome measures

Primary outcome

Number of ICD shocks

Complications

Battery life of ICD and CRT

Secondary outcome

NVT

Study description

Background summary

Patients with life-threatening rhythm disturbances or severe heart failure are candidates for implantation of an internal cardioverter defibrillator (ICD) or cardiac resynchronisation therapy device (CRT). Children and patients with congenital heart disease, however, relatively infrequent undergo ICD or CRT implantation. Therefore, knowledge about long-term consequences and potential complications of these therapies remain scarce.

Study objective

European registry of children and patients with congenital heart disease that undergo ICD or CRT implantation. This will lead to a larger amount of data leading to increased knowledge about long-term consequences and potential complications.

Study design

European registry of children and patients with congenital heart disease that undergo ICD or CRT implantation. After first inclusion data will be updated every year,

Study burden and risks

No extra risks

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Implantation of ICD or CRT in children or patients with congenital heart disease

Exclusion criteria

All patients that could not be categorized as children or patients with congenital heart disease

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2009
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Internal Cardioverter defibrillator
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	16-03-2009
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL23626.058.08