

Microvolt T-Wave Alternans in Adults with Congenital Heart Disease: a Predictor of Ventricular Arrhythmias

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Primary Objective: to determine the prevalence of MTWA in adults with congenital heart disease who are deemed to be at high risk for ventricular arrhythmias and sudden cardiac death. Secondary Objective(s): • to describe the clinical usefulness and...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON44144

Source

ToetsingOnline

Brief title

Microvolt T-wave Alternans in Adults with Congenital Heart Disease

Condition

- Cardiac arrhythmias
- Cardiac and vascular disorders congenital

Synonym

Congenital heart defects; birth defect of the heart

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Congenital heart disease, Microvolt T-wave alternans, Sudden cardiac death, Ventricular arrhythmias

Outcome measures

Primary outcome

The prevalence of MTWA

Secondary outcome

The occurrence of the following events in patients with negative, indeterminate or positive MTWA

- o Ventricular arrhythmias
- o Sudden cardiac death
- o Cardiac death
- o All-cause mortality

Study description

Background summary

Sudden cardiac death (SCD) is one of the main causes of mortality in adults with congenital heart disease. Risk stratification for SCD is difficult, because it is still unclear which risk factors contribute to a heightened risk of SCD.

Implantation of an implantable cardioverter-defibrillator is often complicated mainly by ICD lead or shock generator failure or inappropriate ICD shocks. Previous research has shown that a microvolt T-wave alternans (MTWA) can predict ventricular arrhythmias and SCD within the next 1-2 years in patients with non-ischemic or ischemic cardiomyopathy.

MTWA could also predict SCD and ventricular arrhythmias in adults with congenital heart disease.

Study objective

Primary Objective: to determine the prevalence of MTWA in adults with

congenital heart disease who are deemed to be at high risk for ventricular arrhythmias and sudden cardiac death.

Secondary Objective(s):

- to describe the clinical usefulness and predictive value of MTWA for ventricular arrhythmia events, all-cause mortality and cardiac death.
- Comparison between the MTWA-positive, -indeterminate and -negative groups and between negative and non-negative groups.

Study design

A prospective, multicentre observational study with a minimum follow up duration of one year.

Study burden and risks

Patients will undergo a bicycle exercise test, during which only a moderate exercise is delivered and the heart rate will go up to 120 beats per minute. This is a non-invasive test which is considered to be not hazardous to patients

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

- Diagnosed with a congenital heart defect
- Age ≥ 18 years old
- History of ventricular arrhythmias

or

Implantable cardioverter-defibrillator implanted for primary or secondary prevention of sudden cardiac death

or

A high risk of SCD ($\geq 3\%$ annual risk) according to the risk score or ICD indication according to the consensus statement on arrhythmias in CHD as identified in the PREVENTION-ACHD study (NL50152.018.14).

Exclusion criteria

- Persistent or permanent atrial fibrillation.
- Ventricular pacing
- NYHA class III or IV symptoms
- Inability to perform exercise otherwise

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Will not start

Enrollment: 50
Type: Anticipated

Ethics review

Approved WMO
Date: 24-03-2016
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	NL55036.018.15