The efficacy of flEcainide Compared To metOprolol in reducing Premature ventrIcular Complexes. An open label cross-over study in pediatric patients.

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To test the acute effect of beta-blockers vs flecainide on the reduction of PVCs in a pediatric population. Secondary objectives are to perform a prospective evaluation of the effect of PVCs on LV function, to test the effect of reduction of PVCs by…

Ethical review	Approved WMO
Status	Completed
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON55422

Source
ToetsingOnline

Brief title
ECTOPIC trial

Condition

- Cardiac arrhythmias

Synonym
frequent premature ventricular contractions, frequent ventricular ectopic beats

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: children, left ventricular dysfunction, medical treatment, premature ventricular contractions

Outcome measures

Primary outcome

The acute effect of flecainide and metoprolol on the reduction of PVCs as

measured on Holter registration.

Secondary outcome

The function of the left and right ventricle as measured by echocardiography

and cardiac resonance imaging, and NT-pro-BNP levels in the blood.

Study description

Background summary

Frequent idiopathic premature ventricular contractions (PVCs) and asymptomatic ventricular tachycardia (VTs) in children are rare, but can lead to LV dysfunction. PVCs can be reduced by anti-arrhythmic drug therapy and thereby LV function can be restored. In clinical practice beta-blockers are usually the first line of treatment. We hypothesise that flecainide is more effective in reducing the amount of PVCs than beta-blocker metoprolol.

Study objective

To test the acute effect of beta-blockers vs flecainide on the reduction of PVCs in a pediatric population. Secondary objectives are to perform a prospective evaluation of the effect of PVCs on LV function, to test the effect of reduction of PVCs by beta-blockers or flecainide on LV function and to determine additional risk factors for development of LV-dysfunction.

Study design

In a pediatric cohort of patients the acute effect of beta-blocker vs flecainide on the amount of PVCs will be tested in an open label cross-over

design. In case of clinical symptoms or subclinical signs of LV dysfunction on echocardiography or CMR, the most effective drug will be continued, to evaluate the effect on symptoms or LV dysfunction. The follow-up of these patients will be performed in a prospective observational study.

Intervention

After baseline function testing patients will be randomized to first receive an oral dose of metoprolol (1 mg/kg/dose twice daily) and secondly flecainide (2 mg/kg/dose twice daily) or the other way around. Each drug will be administered for at least 5 consecutive days, after which function testing will be repeated. In between a drug free period of at least two weeks will be implemented, to allow complete clearance of the drug.

Study burden and risks

The burden of the study procedures is limited. Procedures are those routinely performed during regular follow-up in these patients and include physical examination, ECG, echocardiography, Holter registration every 6 months and NT-pro-BNP measurement once a year. In addition, an exercise test will be performed at the start and after medication testing cardiac magnetic resonance imaging will be performed. The risks of medication testing are limited. Both drugs have been used extensively in the age group in which this study is performed and possible side effects are reversible by discontinuation of the drug. Patients will benefit from the study, as they will learn which medication is most effective in reducing PVCs in each individual case.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Age >= 1 year and < 18 years - Structurally normal heart confirmed by echocardiography- PVCs > 15% on two different 24-hour Holter recording- With or without asymptomatic VTniversitai

Exclusion criteria

- Age < 1 year, because of the significant chance of spontaneous resolution of PVCs- Structural cardiac defects- History of cardiac surgery- Myocarditis - Cardiomyopathies- Long QT-syndrome - Catecholaminergic Polymorfic Ventricular Tachycardia (CPVT) - Verapamil sensitive PVC / Ventricular Tachycardia (VT) - Patients with mental retardation === -1 ? 0 : str.le

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-09-2018
Enrollment:	49
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Metoprololsuccinaat Aurobindo
Generic name:	metoprolol
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Tambocor - TEVA
Generic name:	flecainide
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	15-11-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	01-12-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	16-05-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	10-07-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	03-02-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	17-05-2021
Application type:	Amendment
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

ID: 26689
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2017-001037-72-NL
CCMO	NL60023.058.17
OMON	NL-OMON26689

Study results

Actual enrolment: 19