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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Flecainide is more effective in reducing the amount of PVCs than beta-blocker metoprolol.

Ethical review	Not applicable
Status	Pending
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON26689

Source
Nationaal Trial Register

Brief title
ECTOPIC

Condition

- Cardiac arrhythmias

Health condition

frequent premature ventricular contractions frequent ventricular ectopic beats left ventricular dysfunction anti-arrhythmic drugs children frequente premature ventriculaire contracties frequente overslagen van de hartkamers linker kamer dysfunctie anti-aritmica kinderen

Research involving
Human

Sponsors and support

Primary sponsor: Leiden University Medical Center
Leiden, the Netherlands
Source(s) of monetary or material Support: None

Intervention

Explanation

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

Study description

Background summary

Rationale: Frequent idiopathic premature ventricular contractions (PVCs) and asymptomatic ventricular tachycardia (VTs) in children are rare, but can lead to left ventricular (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 metoprolol.

Objective: To test the acute effect of metoprolol 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 metoprolol 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 metoprolol 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 cardiac magnetic resonance imaging, 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.

Study population: Children between 1 year and 18 years of age, a structurally normal heart, more than 15% PVCs on Holter recording and (without) asymptomatic VTs. 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.

Main study parameters/endpoints: The acute effect of flecainide and metoprolol on the reduction of PVCs as measured on Holter registration.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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 pro-brain natriuretic peptide 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.

Study objective

Flecainide is more effective in reducing the amount of PVCs than beta-blocker metoprolol.

Study design

Holter registration: reduction of % of PVCs, before and after medication testing.

Echocardiography: measurement of LV/RV function by two dimensional echocardiography and strain imaging, before and after medication testing.

CMR: assessment of ventricular volumes and function, once baseline measurement.

Intervention

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. 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.

Contacts

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Eligibility criteria

Age
Babies and toddlers (28 days-23 months)
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

- Age ¡Ý 1 year and < 18 years

- Structurally normal heart confirmed by echocardiography

- PVCs > 15% on two different 24-hour Holter recording

- With or without asymptomatic VT

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

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2017
Enrollment:	49
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 55422
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6323
NTR-old	NTR6498
CCMO	NL60023.058.17
OMON	NL-OMON55422

Study results