Medical study in which the efficacy of anti-arrhythmic drugs on ventricular ectopic heartbeats in children will be examined.

Gepubliceerd: 06-02-2017 Laatst bijgewerkt: 19-03-2025

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	Hartritmestoornissen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26689

Bron
NTR

Verkorte titel
ECTOPIC

Aandoening

- Hartritmestoornissen

Aandoening

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

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Leiden, the Netherlands
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

The acute effect of flecainide and metoprolol on the reduction of PVCs as measured on Holter registration.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Leeftijd
Baby's en peuters (28 dagen - 23 maanden)
Adolescenten (12-15 jaar)
Adolescenten (16-17 jaar)

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2017
Aantal proefpersonen:	49
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55422
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten