Extra energy for hearts with a genetic defect

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25078

Source
NTR

Brief title
ENERGY

Health condition

Hypertrophic Cardiomyopathy

Sponsors and support

Primary sponsor: ZonMW en de Hartstichting, Programma Translationeel Onderzoek, project 95105003
Source(s) of monetary or material Support: ZonMW/Hartstichting Programma Translationeel Onderzoek project 95105003

Intervention

Outcome measures

Primary outcome

Myocardial energy efficiency, as measured by PET/CT and CMR

Secondary outcome

Diastolic function measured by echocardiography, volume parameters of the heart measured by CMR, exercise capacity measured by CPET, electrophysiological properties of the heart measured by ECG

Study description

Background summary

Aims: Previous studies have shown that HCM mutation carriers have a decreased myocardial energy efficiency, which is thought to play a key role in the pathomechanism of HCM. The ENERGY trial aims to determine whether metabolic drugs correct decreased myocardial energy efficiency in HCM mutation carriers at an early disease stage.
Methods: 40 genotype-positive, phenotype-negative MYH7 mutation carriers will be treated for two months with trimetazidine or placebo in a double-blind randomized study design. Directly before and after treatment, study subjects will undergo an [11C]-acetate PET/CT and CMR scan to measure myocardial energy efficiency. Myocardial efficiency will be calculated as the amount of oxygen used by the heart to perform work.
Conclusion: The ENERGY trial will be the first proof-of-concept to determine whether metabolic drugs are a potential preventive therapy for HCM. Given that trimetazidine is already used in clinical practice, there is large potential to swiftly implement this drug in HCM therapy.

Study objective

Trimetazidine improves myocardial energy efficiency in MYH7 mutation carriers

Study design

Last patient last visit

Intervention

Trimetazidine 20mg 3dd

Contacts

Public
Amsterdam UMC, location VUmc, Department of Physiology
Beau van Driel

+31620673492

Scientific
Amsterdam UMC, location VUmc, Department of Physiology
Beau van Driel

+31620673492

Eligibility criteria

Inclusion criteria

18-65 years old
Class 5 MYH7 mutation identified by pre-symptomatic genetic screening

Exclusion criteria

Cardiovascular disease
- Hypertrophic Cardiomyopathy (Maximal Wall Thickness >15mm)
- Wall motion disorders
Diabetes mellitus
Any absolute or relative contra-indication for MRI (i.e. metallic implants and claustrophobia)
Inability to give informed consent.
Severely impaired renal function with a GFR < 30 ml/min
Parkinson disease and related symptoms

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2019
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	01-02-2019
Application type:	First submission

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
NTR-new	NL7492
Other	METC VUmc : 2018.344

Study results