Improvement of ischemia and myocardial blood flow in patients with ischemic cardiomyopathy after treatment with Electric Shock Wave Therapy using CMR

Published: 29-10-2008
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Primary Objective: Improvement in myocardial blood flow and reverse remodelingSecondary Objective(s): Improvement in wall motion abnormalities, left ventricular function and NYHA class

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON33662

Source
ToetsingOnline

Brief title
Electric Shock Wave Therapy

Condition

- Heart failures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Heart failure, ischemic cardiomyopathy

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Angioneogenesis, Ischemic Cardiomyopathy, MRI, Shockwave therapy

Outcome measures

Primary outcome

Improvement in myocardial blood flow and occurrence of reverse remodeling after

treatment of patients with Ni-Cath based on MRI.

Secondary outcome

Secondary endpoints consist of wall motion abnormalities, left ventricular

function, and improvement in NYHA class based on MRI and Quality Of Life score.

Study description

Background summary

Management of patients with ischemic cardiomyopathy is a major challenge for the cardiologist and cardiac surgeon. Patients with advanced ischemic cardiomyopathy frequently have limited symptoms with recurrent angina, angina at low work thresholds, breathlessness, and other debilitating conditions. Surgical and interventional options for these patients typically have been exhausted or will result in only partial revascularization. Therefore, therapy remains limited to the use of multiple anti-anginal medications, reduced activity, exertion, and stress level, and significant alteration and limitation of lifestyle.
A new Non-Invasive Cardiac Angiogenesis Therapy (NI-CATh) was developed recently which couples the ability of low intensity shock waves to induce angiogenesis to the therapy of angina and is becoming a new alternative in the treatment of these patients.
The NI-Cath will lead to a decrease of the size of the ischemic zone and an improvement in myocardial blood flow, reverse remodeling and NYHA class in patients with ischemic cardiomyopathy

Study objective

Primary Objective: Improvement in myocardial blood flow and reverse remodeling
Secondary Objective(s): Improvement in wall motion abnormalities, left ventricular function and NYHA class

Study design

Since there will be no control group and thus there is no randomization, the study will be performed as a longitudinal study.

Study burden and risks

The research involves a low burden, which consists of a frequent visit to the outpatient clinic for the treatment with the device. There are no known major adverse events with the use of the device, so the risk for the subject is also low.

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

* Patient is male or female 18 years or older.
* Patient is diagnosed with ischemic cardiomyopathy. I.e. a significantly impaired left ventriculair dysfunction (left ventricular ejection fraction * 35 to 40 percent) that results from coronary artery disease based on a coronary angiogram.
* Patient has documented myocardial segments with reversible ischemia and or hibernation.
* Patient is classified as NYHA class II-IV.
* Patient should be on a stable dosage of medication used to treat angina for at least 6 weeks prior to enrollment.
* Patients where angioplasty and bypass are not indicated because of anatomical or procedural reasons or frequent reocclusion / restenosis following traditional revascularization.
* Patient has refused to undergo another angioplasty or CABG.

Exclusion criteria

* Patient has chronic lung disease including emphysema and pulmonary fibrosis.
* Patient has active endocarditis, myocarditis or pericarditis.
* Patient is simultaneously participating in another device or drug study, or has participated in any clinical trial involving an experimental device or drug, including other drugs or devices enhancing cardiac neovascularization.
* Patients who are unwilling or unable to cooperate with study procedure.
* Patients with renal dysfunction with eGFR<30 ml/min
* Patients who are unwilling to quit smoking during the study procedure (including screening phase)
* Patients who had MI less than 3 months prior to treatment
* Patients who are diagnosed with a 3rd and 4th degree heart valve disease.
* Patient with intraventricular thrombus
* Patient is pregnant
* Patient with a malignancy in the area of treatment

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-05-2009
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO Date:	29-10-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-03-2010
Application type:	Amendment
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	NL23935.029.08