Patients with Angina and MicrOvaScular DysfunctIon treaTed with cardiac non-InVasivE SHOCK wave therapy, a first in man pioneering trial -POSITIVE SHOCK-

Published: 20-06-2023
Last updated: 22-02-2025

Problem definition and objectivesThe microcirculation can only be measured by coronary blood flow parameters during catheterization. Patients with MVD will be offered an unique first in man non-invasive therapy namely: external low intensity shock...

Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON53243

Source
ToetsingOnline

Brief title
POSITIVE SHOCK trial

Condition

- Coronary artery disorders

Synonym
Microvascular dysfunction, small vessel disease

Research involving
Human

Sponsors and support

Primary sponsor: cardiologie
Source(s) of monetary or material Support: Zuyderland Medisch Centrum beurs en eventueel nog andere beurzen indien toegekend

Intervention

Keyword: coronary physiology, Female predisposition, Low intensity Externe Shockwave therapy, Microvascular dysfunction

Outcome measures

Primary outcome

Primary endpoint

The primary endpoint at 6 months is:

- Improvement of the index of microvascular resistance (IMR)

Secondary outcome

The secondary outcomes at 6 months are:

- Improvement in invasive parameter of MVD measured as coronary flow reserve

(CFR)

- Self (patient)-assessed angina score and quality of life, assessed with the

Seattle Angina and SF-36 Questionnaire

- Improvement of exercise capacity measured in metabolic equivalents (MET)

scores during bicycle test

- Use of short-acting nitrates

Study description

Background summary

Angina is generally ascribed to obstructive coronary artery disease (CAD, but

40% does not have CAD on catheterization. For a long time these patients were not recognized in their symptoms with a predominance in female patients. However, there is much more to coronary circulation beyond epicardial arteries namely the microvasculature which is a complex and structured system of small vessels (<400µm) which adapt their function in order to sustain the myocardium*s physiological needs. The clinical importance of this vascular compartment has become apparent in light of the significant proportion of patients presenting signs and symptoms of myocardial ischemia, despite the absence of epicardial disease. Patients with coronary microvascular dysfunction (MVD) have increased cardiovascular risk, high morbidity and impaired quality of life. Therefore they are a source of considerable health resource utilization as no interventional therapies exist. The only treatment option is an extensive mix of medication which is often inadequate and hampered by its side-effects.

Study objective

Problem definition and objectives
The microcirculation can only be measured by coronary blood flow parameters during catheterization. Patients with MVD will be offered an unique first in man non-invasive therapy namely: external low intensity shock wave (LiSW). This therapy has been shown to be effective in small trials, which have been done in patients with refractory angina and severe coronary artery disease beyond repair. LiSW therapy improves blood flow by promoting neovascularization and ameliorating inflammatory processes. We will test whether LiSW improves microvascular dysfunction by measuring coronary blood flow parameters before and after therapy and if it improves angina status.

Study design

Patients with mivrovascular dysfunciton are identified during their initital coronary angiogram.
After informed consent they will receive the Low intensity Shock Wave treatment. The protocol consist of 3 treatment er week at baseline, 1 months and 2 months (in total 9 sessions). Per session 3-10 areas are treated with the Cardiospec shockwave. 4 months thereafter a new coronary angigoram will be repeated to asses if improvement of microvascular dysfunction has occured.

Furthermore, patients will undergo a bicycle test and a health care questionnaire at baseline en follow-up.

Study burden and risks

No adverse events are to be expected from the CE marked medical product namely low-intensity shockwave therapy which has been studied in >1000 patients. After shock wave therapy patients will receive another coronary angiogram with

invasive measurements for microvascular function. The first investigation was performed for clinical needs, the second one during follow-up for research purposes. The potential risks are the same, namely rhythm disorder, chest pain, allergic reaction to the contrast fluid, hematoma or infection. There are several potential severe complications such as wire perforation, injury to heart or brain by thrombo- or cholesterol embolism which is estimated to be less than 1 in 1000 patients

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

1. Stable Angina, defined as: - Angina with exercise or rest - Exertional dyspnea 2. Age >=18 years 3. Angina without flow limiting CAD defined as

epicardial stenosis <50% or FFR >0.80 4. presence of MVD defined as IMR> 30

Exclusion criteria

* noncardiac origin of chest pain, such as gastrointestinal or musculoskeletal * Recent (<3 months) myocardial infarction * Severe aortic valve stenosis/ elevated LVEDP * History of coronary artery bypass graft * Known cardiomyopathy or myocarditis * Bad acoustic windows in supine position * LV thrombus * ICD/ pacemaker * Extra-cardiac illness that is expected to limit survival to less than 1 years * Active participation in another trial * Unable to give informed consent or potential for noncompliance with the study protocol in the judgment of the investigator * Pregnant at the time of screening or unwilling to use effective birth control measures

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2023
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Generic name:	Cardiospec
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-06-2023
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	30-01-2025
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL84092.096.23