ISRCTN68966125 https://doi.org/10.1186/ISRCTN68966125

Treatment of refractory angina pectoris by shock wave therapy

Submission date	Recruitment status	[_] Prospectively registered
23/02/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/04/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/04/2019	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Muhammad Saadat

Contact details
B-84
Gulshan-e-Iqbal
Block 13-D/1
Karachi
Pakistan
-

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00776568

Secondary identifying numbers
URG/UQ/002/01

Study information

Scientific Title
Extracorporeal shock wave therapy (ESWT) for the treatment of refractory angina pectoris

Study objectives
Patients with advanced coronary artery disease (CAD) frequently have limited symptoms with recurrent angina, angina at low work thresholds, breathlessness, and other debilitating conditions. These patients have often been through several "re-do" coronary bypass procedures and multiple percutaneous coronary interventions.

Surgical and interventional options for these patients typically have been exhausted or will result in only partial revascularisation. 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.

The goal of this emerging approach is to therapeutically induce the growth and development of new vasculature in zones of severe ischemia in the myocardium, with the hope that new capillaries and arterioles generated will connect to remnant existing vasculature. These neovessels are viewed to act as collaterals, perfusing ischemic territories unapproachable by macro procedures such as angioplasty and bypass surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The IEC/IRB, City Medical Committee, Karachi (Pakistan). Date of approval: 25/02/2008 (ref: ERB /KIHD/001)

Study design
Randomised controlled single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Coronary artery disease

Interventions
In this study, all participants will receive the same interventions (there is no control group). Each participant will serve as their own control; comparison will be made between their first SPECT and follow-up SPECT.

Efficacy:
1. The patient will be positioned on the treatment table and connected to the ECG monitor.
2. The treatment area to be treated will be localized by cardiologic ultrasound.
3. The treatment area should be divided to a 1 x 1 cm zones. At least three (minimum zones) different myocardial zones are to be treated with shock waves.
4. Ultrasound gel must be applied on the shock wave applicator (SWA) membrane and on the patient's chest skin that is in contact with the SWA. The SWA will be mounted to the Cardiospec according to the ultrasound localisation of the treatment area. The SWA membrane should be inflated to achieve full contact with the patient's skin.
5. Shock waves are applied concomitantly with ultrasound imaging on the myocardial locations.
6. The energy level will be a flux density of 0.09 mj/mm2, and will remain at this level throughout each session. Each myocardial zone will be treated with approximately 100 shocks.
7. At least 2,700 shocks will be applied over a course of 9 treatment sessions.

Safety - the following will be monitored during the interventions:
1. Incidence of patient complications
2. Adverse reactions
3. Rise in cardiac enzymes
4. Blood count
5. Troponin levels
6. Electrocardiogram (ECG) changes

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Therapeutic effect. The following will be assessed at baseline and 6 months post baseline or at the last visit for patients who terminate prematurely:
1.2. Alleviation of anginal symptoms
1.2. Improved myocardial perfusion
1.3. To determine whether the shock wave therapy serves as an adjuvant therapy for the treatment of refractory angina pectoris

2. Change in maximal stress exercise capacity testing. The change in total exercise time assessed using the modified Bruce exercise test, from baseline to 6 months post-baseline, or to the last visit for patients who terminate prematurely.

Secondary outcome measures
1. Change in cardiac enzymes before and after the first treatment
2. The change in SPECT in perfusion from baseline to 6 months post-baseline (17 segments model)
3. AP CCS Stage: The AP CCS Stage at 6 months post-baseline, or at the last visit for patients who terminate prematurely

4. The change in the number of angina attacks from baseline to 6 months post-baseline. The number of attacks per week will be documented
5. Hospital Admission Rate: The change in the number of hospital admission from baseline to 6 months post-baseline. The number of admissions per month will be documented.

Overall study start date
26/02/2008

Completion date
28/11/2008

Eligibility

Key inclusion criteria
1. Male or female, 18 years or older.
2. Diagnosis of chronic stable angina pectoris. Diagnosis is based on medical history, complete physical evaluation, and Exercise Single-Photon Emission Computed Tomography (Exercise SPECT).
3. Patient has documented myocardial segments with reversible ischemia and or hibernation.
4. Patient is classified as AP CCS of III or IV.
5. Patient should be on a stable dosage of medication used to treat angina for at least 6 weeks prior to enrollment.
6. Patients demonstrates exercise tolerance time (ETT) duration <10 minutes on a modified Bruce protocol on 2 consecutive tests (tests no less than 24 hours and no more than 2 weeks apart), with the second test within 25% of the first (Patients should not be informed of exercise restrictions required for entry into the study).
7. Patient has refused to undergo another angioplasty or CABG.
8. Patient has signed an informed consent form.
9. Patient's condition should be stable and should have a life expectancy of >12 months.
10. Patient's current and past medical condition and status will be assessed using previous medical history, physical evaluation, and the physicians (principle investigator's) medical opinion.
11. Newly diagnosed type II diabetes.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria

1. Chronic lung disease including emphysema and pulmonary fibrosis.
2. Active endocarditis, myocarditis or pericarditis.
3. Patient is simultaneously participating in another device or drug study, or has participated in any
4. Clinical trial involving an experimental device or drug, including other drugs or devices enhancing cardiac neovascularization, or any ESWT machine for neovascularization of a competitor company within 3 months of entry into the study.
5. Patients who are unwilling or unable to cooperate with study procedure.
6. Patients who are unwilling to quit smoking during the study procedure (including screening phase)
7. Patients who had myocardial infarction (MI) less than 3 months prior to treatment.
8. Patients who are diagnosed with a 3rd and 4th degree heart valve disease.
9. Patient with intraventricular thrombus.
10. Pregnancy.
11. Patient with a malignancy in the area of treatment.

Date of first enrolment
26/02/2008

Date of final enrolment
28/11/2008

Locations

Countries of recruitment
Pakistan

Study participating centre
B-84
Karachi
Pakistan
-

Sponsor information

Organisation
UNIQUIP International (Pakistan)

Sponsor details
3/87, Faran Co-op. Housing Society
Karachi
Pakistan
-

Sponsor type

Industry

Funder(s)

Funder type
Industry

Funder Name
Government and private collaboration:

Funder Name
UNIQUIP International (main funder) (Pakistan)

Funder Name
City District Government Karachi (funding the investigator and providing facility) (Pakistan)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2012	20/02/2019	Yes	No