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Can a vibratory back massage induce neo-coronary growth? A blinded, randomized controlled pilot study protocol

Submission date 27/08/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered
		[_] Protocol
Registration date 01/09/2015	**Overall study status** Completed	[_] Statistical analysis plan
		[_] Results
Last Edited 29/09/2016	**Condition category** Circulatory System	[_] Individual participant data
		[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Coronary artery disease (CAD), also known as ischemic heart disease, is one of the leading causes of death worldwide. CAD develops because of the build-up of fatty deposits (plaque) on the walls of the coronary arteries (the arteries that supply the heart with oxygen-rich blood). CAD includes a number of diseases, such as angina (pain or pressure in the chest), which is worsened by physical activity or stress. The current treatments for CAD focus on relieving the symptoms and reducing the risk of a heart attack (myocardial infarction). New treatments are emerging, using adult stem cells from patients' own bodies to re-build heart tissue (neocardiogenesis). The aim of this study is to find out whether the use of low frequency vibration massage will help stimulate the growth of new heart tissue in patients with CAD.

Who can participate?
Adults suffering from either angina or ischemic heart disease, who have been deemed unsuitable for heart surgery.

What does the study involve?
Participants are divided into two groups, based on the condition they are suffering from. These groups are then randomly allocated into two further groups who receive different treatments daily. Those in the first group receive half hour sessions of high setting (penetrative) vibration to their upper back via the Vibro-Acoustic Therapy system. Those in the second group receive low setting (non-penetrative) sham therapy to their lower back. The extent of their heart disease and how well their hearts are functioning is measured before the therapy, immediately after, and again three and six months after the therapy.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement of the symptoms of their disorders. There are no long term risks to participants of the study, however continuously applied LFV may be a mild stressor to the heart in some cases angina and /or a sensation of shortness of breath may be temporarily brought on by the treatment.

Where is the study run from?
False Creek Surgical Centre (Canada)

When is the study starting and how long is it expected to run for?
August 2015 to August 2017

Who is funding the study?
Ahof Biophysical Systems Inc. (Canada)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Coronary Revascularization by ExtrAcorporeal Transthoracic Epi-myocardial VIBration

Acronym
CREATE-VIB trial

Study objectives
Penetrative upper back 35 Hz sinusoidal Low Frequency Vibration massage applied daily for 30 minute sessions over a 3 month period via the VTS – 1000 Vibro-Acoustic Therapy system will stimulate neo-coronary growth, enhance myocardial perfusion, and improve clinical outcomes in Refractory Angina and/or Ischemic Heart Failure patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
A single center prospective blinded interventional randomized controlled pilot study.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Refractory Angina (CCS anginal class 3 or 4), and/or Ischemic Heart Failure (NYHA functional class 2, 3 or 4).

Interventions
Thirty ischemic heart test subjects will be divided into two parallel groups matched for condition and class, where-after the groups will be randomized to receive half hour sessions of penetrative (high setting) 35 Hz vibration via the VTS – 1000 Vibro-Acoustic Therapy system to their upper back vs. non-penetrative (low setting) sham therapy. Interventions planned daily (with a minimum compliance rate of 75%) - over a 3 month period.

Intervention Type
Device

Primary outcome(s)
1. Stress SPECT MPI (maximal exercise) to assess myocardial perfusion by global perfusion at rest (SSS – Summed Stress Score) and stress (SRS – Summed Rest Score), pre vs. post therapy. Time to 1 mm and 2 mm ST depression, time to and degree of anginal symptoms, and functional capacity (total time on treadmill) should be additionally noted on a case by case basis.
2. Stress Echo (maximal exercise) to assess evaluation of inducible RWMAs by hypo-akinetic segment count and Wall Motion Score Index (WMSI) - pre vs. post therapy.
3. Walking test (20 to 100 meter; patient encouraged to walk as long and as brisk as possible) to assess NHYA heart failure classification and CCS anginal class- pre vs. immediate post, 3 months and 6 months post therapy.

Key secondary outcome(s))
1) Anginal count by month long diary record (average frequency of anginal episodes per day), pre vs. immediate post, three and six months post therapy.
2) Nitroglycerine (NTG) use count by month long diary record (average frequency of NTG usage per day), pre vs. immediate post, three and six months post therapy.

Completion date
12/08/2017

Eligibility

Key inclusion criteria
1. Adults (> 35 years of age)
2. Patient weight up to 120 kg
3. Stable, CCS class 3 or 4 angina pectoris, and/or NYHA functional class 2, 3 or 4 ischemic heart failure
4. A positive Exercise Treadmill Test (ETT), and at least one of a Nuclear SPECT MPI perfusion study showing evidence for reversible myocardial ischemia, and/or a Stress Echo showing at least one provoked Regional Wall Motion Abnormality (RWMA)
5. An interpretable QRS complex enabling ST analysis during stress testing (i.e. no left bundle branch block–LBBB, or paced beats during stress)
6. Ability to present for daily hospital appointments (with a minimal expected compliance of at least 75%), over a three month period
7. Patient was declined to Coronary Artery Bypass Graft (CABG) surgery and / or Percutaneous Coronary Intervention (PCI) by the attending cardiologist or surgeon, and has no plans to undertake other forms of coronary angiogenic therapy (e.g. EECP, ESMR etc.) during the study period
8. Patient has received optimized medical therapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Left bundle branch block (LBBB)
2. Paced Rhythm
3. Severe Aortic Stenosis (valve area up to 1.0 cm2)
4. Patient’s weight greater than 120 kg
5. Cannot walk on treadmill

Date of first enrolment
02/01/2016

Date of final enrolment
02/01/2017

Locations

Countries of recruitment
Canada

United States of America

Study participating centre
False Creek Surgical Centre
555 West 8th Avenue
Vancouver, British Columbia
Canada
V5Z 1C6

Sponsor information

Organisation
Ahof Biophysical Systems Inc.

Funder(s)

Funder type
Industry

Funder Name
Ahof Biophysical Systems Inc.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date