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The evaluation of Individual Shear Rate Therapy on the hemodynamic and molecular effect in patients with peripheral artery disease

Submission date
17/02/2014

Recruitment status
No longer recruiting

Registration date
14/05/2014

Overall study status
Completed

Last Edited
02/02/2015

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Peripheral artery disease (PAD) is a cardiovascular disease of the lower limbs, in some cases causing leg pain when walking (intermittent claudication). A severe PAD increases the risk of other cardiovascular diseases (such as coronary heart disease) and may result in foot amputation. This is an initial study which will evaluate the effect a training concept called the Individual Shear Rate Training (ISRT) on peripheral circulation of patients with PAD.

Who can participate?
Patients aged 50 to 85 years old and suffering from PAD. 13 participants to be recruited.

What does the study involve?
Five weeks before the ISRT treatment, normal peripheral circulation will be assessed by a number of tests and measurements. Then participants will undergo 30 hours of ISRT over 5 weeks. To undergo ISRT, the participant lies down, gets pneumatic cuffs wrapped around the lower and upper thighs and is connected to a monitor for heart rate and cardiac rhythm. The cuffs inflate at the beginning of the relaxation/filling phase of the heart and deflate at the beginning of the ventricular contraction. ISRT increases fluid shear stress in the circulation, thereby increasing the growth of biological bypasses (arteriogenesis or increase in diameter of blood vessels). One ISRT cycle lasts 90 minutes, 5 days a week over 5 weeks.

What are the possible benefits and risks of participating?
No provided at time of registration

Where is the study run from?
Charité Universitätsmedizin Berlin (Germany)

When is the study starting and how long is it expected to run for?
March 2014 to July 2014

Who is funding the study?
Charité Universitätsmedizin Berlin (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Individual Shear Rate Therapy on the hemodynamic and molecular effect in patients with peripheral artery disease

Acronym
ISRT II

Study objectives
It is hypothesised that Individual Shear Rate Therapy (ISRT) treatment improves arterial blood flow velocity in patients with occluded femoral-popliteal arteries. The hypothesis is that there will be an enhancement in endothelial function, Ankle-Brachial Index (ABI), walking distance, quality of life, electrical cardiometry, relative pulse slope index (rPSI) and Electrical Cardiometry (EC™), Cardiotronic's patented algorithm, for measurement of several hemodynamic parameters, such as stroke volume and cardiac output, as well as blood collection for the

measurement of molecular parameters such as protein expression analysis (e.g., leukocyte telomerase activity), DNA expression analysis (e.g., leukocyte telomere length) , RNA expression analysis (e.g., iNOS), NO plasma levels, and plasma secretome analysis for endothelial monoculture as well as endothelial cells and smooth-muscle cells co-culture assays before and after ISRT vs control.

On 02/02/2015 the trial record was updated to change all references to Personal Shear Rate Therapy (PSRT) to Individual Shear Rate Therapy (ISRT).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Campus-Virchow-Klinikum, University Medical Centre Berlin, Ethics Committee, 24/10/2013, ref: EA2/140/13

Study design
Open comparative controlled prospective clinical pilot study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

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
ISRT effects on Peripheral arterial disease (PAD)

Interventions
Thirteen patients with peripheral artery disease will be enrolled in a pre-test and post-test controlled trial and undergo 30 hours of individual shear rate therapy (ISRT) over 5 weeks and a control period of another 5 weeks prior to the intervention in which the natural course of peripheral circulation will be assessed.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Change of endothelial function measured with flow-mediated dilation (FMD) and nitro-mediated dilation (NMD) using a high-definition ultrasound-system (HD11XE Philips) in the brachial artery, measured directly before and after ISRT as well in a control phase 5 weeks prior to treatment start

Secondary outcome measures
1. The relative Pulse Slope Index (rPSI) measured by ultrasound
2. The FMD of the common femoral artery measured by ultrasound
3. The Initial Claudication Distance (ICD) measured by the treadmill test with 3.5 km/h and 12% elevation
4. The Absolute Claudication Distance (ACD) measured by the treadmill test with 3.5 km/h and 12% elevation
5. Ankle-Brachial Index (ABI)
6. Quality of Life Questionnaire (Short-Form 36)
7. Electrical cardiometry ('Window to the heart' Osypka Medical GmbH)
8. Molecular parameters such as protein expression analysis (e.g., leukocyte telomerase activity), DNA expression analysis (e.g., leukocyte telomere length) , RNA expression analysis (e.g., iNOS), NO plasma levels, and plasma secretome analysis for endothelial monoculture, as well as endothelial cell and smooth muscle cell co-culture assays. Measured by qRT-PCR, western blot or ELISA, respectively

Each outcome will be measured directly before and after ISRT as well in a control phase 5 weeks prior to treatment start. Likewise, for molecular analysis volunteer blood samples are collected at the beginning of 5 weeks of a control phase, before and after 45 minutes of ECP treatment and after 30 hours of ECP treatment.

Overall study start date
01/03/2014

Completion date
01/07/2014

Eligibility

Key inclusion criteria
1. Age 50 to 85 years
2. Fontaine classification for PAD II
3. Stable claudication over the last 5 weeks
4. Femoral-popliteal occlusion with one perfused calf artery
5. Willing to be assigned to any of the study intervention arms

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants

13

Key exclusion criteria
1. Smoking
2. Arrhythmia
3. Spastic palsy
4. Aortic valve insufficiency >II°
5. Acute deep vein thrombosis at the lower extremity
6. Dementia or severe cognitive disorder/mental retardation
7. Participation in another clinical trial

Date of first enrolment
01/03/2014

Date of final enrolment
01/07/2014

Locations

Countries of recruitment
Germany

Study participating centre
Mittelallee 11
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Sponsor information

Organisation
Charité Berlin Center for Cardiovascular Research (CCR) (Germany)

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Sponsor type

University/education

Website
http://www.ccr.charite.de/en/about_us/

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
University/education

Funder Name
Charité Universitätsmedizin Berlin (Germany)

Alternative Name(s)
Medical School - Charité - University Medicine Berlin

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

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