ISRCTN77215948 https://doi.org/10.1186/ISRCTN77215948

Art.Net Brain I Trial: To determine whether external counterpulsation positively affects cerebral blood flow in patients with stenotic or occluded cerebral arteries

Submission date
26/06/2012

Recruitment status
No longer recruiting

Registration date
16/07/2012

Overall study status
Completed

Last Edited
17/04/2019

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this study is to find out whether external counterpulsation (ECP) improves the blood flow of patients with stenotic (narrowed) or occluded (blocked) cerebral arteries (brain-supplying blood vessels).

Who can participate?
Patients aged over 60 with stenosis (narrowing) or occlusion (blockage) of one of the internal carotid arteries (the major blood vessels in the neck that supply blood to the brain, neck, and face)

What does the study involve?
Participants are randomly allocated to undergo either ECP treatment followed by sham ECP treatment, or undergo the same procedures in the reverse sequence. To undergo ECP, the patient lies down, has pneumatic (inflatable) cuffs wrapped around their calves and lower and upper thighs, and is connected to a heart monitor. The cuffs inflate at the beginning of the filling phase of the heart and deflate at the beginning of the contraction. Sham ECP is done with inflation pressures that are lower than the pressure required for a beneficial effect. One ECP cycle lasts 20 minutes. During ECP, assessments are carried out continuously including: ultrasound examination of the median carotid artery, blood pressure measurement, and electrocardiogram (ECG) recording the electrical activity of the heart. Assessments are also carried out before ECP, in between treatment cycles, after ECP and at 1-month follow-up.

What are the possible benefits and risks of participating?
The assessments may aid in the diagnosis of blood vessel disease and may lead to changes in treatment. ECP may provide a non-invasive way to increase the blood flow of patients with stenosis of the carotid/cerebral arteries. ECP has been shown to be safe in patients with blood vessel disease. Side effects may include superficial skin abrasions, redness and muscular pain during the first cycle. Therefore, participants are offered protective pants to wear underneath

the cuffs. The Berlin ECP centre has used these on patients with long-term ECP sessions and successfully avoided side effects.

Where is the study run from?
1. Charité Universitätsmedizin Berlin (Germany)
2. Albert-Ludwigs-Universität Freiburg (Germany)

When is the study starting and how long is it expected to run for?
July 2012 to November 2012

Who is funding the study?
1. Charité Universitätsmedizin Berlin (Germany)
2. Albert-Ludwigs-Universität Freiburg(Germany)

Who is the main contact?
Dr Eva-Elina Buschmann

Contact information

Type(s)
Scientific

Contact name
Dr Eva Elina Buschmann

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Art.Net Brain I Trial: A prospective, randomised, controlled trial to assess the effect of external counterpulsation on cerebral hemodynamics in patients with hemodynamically relevant stenosis or occlusion of the cerebral arteries

Study objectives
It is hypothesised that external counterpulsation (ECP) treatment improves cerebral blood flow velocity in patients with stenotic or occluded cerebral arteries.

The null hypothesis is that there will be no difference in blood flow velocity following ECP or Sham treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Albert-Ludwigs-Universitaet Freiburg, University Medical Center Freiburg, Ethics Committee, 27/01/2011, ref: EK 24/11

Study design
Open comparative randomized controlled prospective clinical pilot study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
ECP effects on cerebral artery stenoses

Interventions
The study will involve 24 patients >60 years of age with a unilateral >80% stenosis (local stenosis grade) or occlusion of the internal carotid artery, who are willing to be assigned to any of the study intervention schemes, recruited at the University Medical Center Freiburg, Department of Neurology, Freiburg, Germany. Participation will be over a one-month period (until last follow-up). Participants will be assigned to one cycle of ECP-active followed by one cycle of ECP-sham or vice versa.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Mean cerebral blood flow velocity (CBFVmean) in the A. cerebri media ipsilateral and contralateral to the stenosis of the internal carotid artery before, during and after ECP therapy (ECP active and ECP sham)

Secondary outcome measures
1. CO2 reactivity (CO2normo, CO2hyper) before and after ECP active and ECP sham
2. CO2RHb, CO2RHbOx, CO2RHbRed before and after ECP active and ECP sham
3. Trans cranial Doppler envelope curve analysis (Vsystolisch max, Vdiastol. max, systolic and diastolic acceleration, PI and RI) before, during and after ECP active and ECP sham
4. Parameters of dynamic cerebral autoregulation (phase shift; spontaneous fluctuation) before, during and after ECP active and ECP sham
5. Cerebrovascular resistance before, during and after ECP active and ECP sham
6. Baro receptor reflex sensitivity before, during and after ECP active and ECP sham
7. Near infrared spectroscopy (TOI, THI, HbTot, HbOx, HbRed) before, during and after ECP active and ECP sham
8. Fow-volume analysis of the distal extracranial segment of the internal carotid artery before, during and after ECP active and ECP sham

Overall study start date
01/07/2012

Completion date
30/11/2012

Eligibility

Key inclusion criteria
1. Age >60 years
2. Unilateral >80% stenosis (local stenosis grade) or occlusion of the internal carotid artery
3. Willing to be assigned to any of the study intervention schemes

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
24

Total final enrolment
28

Key exclusion criteria
1. Contralateral stenosis of the carotid artery >70%
2. No transtemporal acoustic window for transcranial Doppler sonography, cerebral ischemic

event <3 moths prior
3. Atrial fibrillation or flutter
4. Severe arterial hypertension (>180 mmHg systolic, >100 mmHg diastolic)
5. Cardiac ejection fraction <35%
6. Aortic valve insufficiency >II°
7. Tricuspid valve insufficiency >III°
8. Aortofemoral or femoropopliteal bypass
9. Recent thrombosis of lower extremity
10. Hemorrhagic diathesis or clinical signs thereof
11. Dementia or severe cognitive disorder/mental retardation
12. Participation in another clinical trial

Date of first enrolment
01/07/2012

Date of final enrolment
30/11/2012

Locations

Countries of recruitment
Germany

Study participating centre
Charité Universitätsmedizin Berlin
Berlin
Germany
D-13353

Sponsor information

Organisation
Charité University Medicine Berlin (Charité Universitätsmedizin Berlin) (Germany)

Sponsor details
Augustenburger Platz 1
Berlin
Germany
D-13353

Sponsor type
University/education

Website
http://www.charite.de

Organisation
Universitätsklinikum Freiburg

Sponsor details
Abteilung für Neurologie
Breisacherstr. 64
Freiburg
Germany
79106

Sponsor type
University/education

Organisation
Charité

Sponsor details

Sponsor type
Not defined

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

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Charité Universitätsmedizin Berlin

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

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Funder Name
Albert-Ludwigs-Universität Freiburg

Alternative Name(s)
Albert Ludwig University of Freiburg, University of Freiburg, Uni Freiburg

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2018	17/04/2019	Yes	No