

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

<b>Submission date</b> 26/06/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/07/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/04/2019	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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

**Contact details**

Fachaerztin für Innere Medizin  
Charité Universitätsmedizin Berlin, CVK  
Augustenburger Platz 1  
Berlin  
Germany  
D-13353

## Additional identifiers

**Protocol serial number**

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

### **Study type(s)**

Treatment

### **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(s)**

Mean cerebral blood flow velocity (CBFV<sub>mean</sub>) 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)

### **Key secondary outcome(s)**

1. CO<sub>2</sub> reactivity (CO<sub>2</sub>normo, CO<sub>2</sub>hyper) before and after ECP active and ECP sham
2. CO<sub>2</sub>RHb, CO<sub>2</sub>RHbOx, CO<sub>2</sub>RHbRed before and after ECP active and ECP sham
3. Trans cranial Doppler envelope curve analysis (V<sub>systolisch</sub> max, V<sub>diastol.</sub> 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. Flow-volume analysis of the distal extracranial segment of the internal carotid artery before, during and after ECP active and ECP sham

**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

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**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 months 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)

## Organisation

Universitätsklinikum Freiburg

## Organisation

Charité

## 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

### 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?
<a href="#">Results article</a>	results	01/11/2018	17/04/2019	Yes	No