

Acupuncture-induced changes on brain excitability and interhemispheric interaction for healthy subject

Submission date 24/01/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/01/2017	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/11/2020	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Acupuncture is a form of traditional Chinese medicine, which has been used to treat a range of medical conditions. It has been used as a treatment for the rehabilitation of stroke patients with one-sided weakness (hemiparesis) for decades, and has been shown to help in the recovery of movement (motor recovery). The reason for this is unknown, however some believe that the acupuncture causes new connections in the brain to form in order to use new pathways to avoid the old, affected ones (neuroplasticity). The aim of this study is to use a type of brain scanning to find out whether acupuncture can lead to neuroplastic changes in the brain in healthy adults.

Who can participate?

Ten healthy adult volunteers.

What does the study involve?

Participants are allocated to undergo two treatment periods in a random order, with seven days of no treatment in between. The first treatment period involves 30 minutes of acupuncture. This involves having acupuncture needles applied to acupoints (locations on the body affected by acupuncture) in the left hand, arm and lower leg, which are then moved around to create an aching, tingling sensation. The second treatment involves sitting in a comfortable chair whilst being relaxed and alert for 30 minutes. Before and 10 minutes after each treatment period, participants in both groups have a brain scan to see if the treatment has had any effect on the brain.

What are the possible benefits and risks of participating?

There are no direct benefits or risks involved for those participating in this study.

Where is the study run from?

Beijing Hospital of Traditional Chinese Medicine (China)

When is the study starting and how long is it to run for?

December 2015 to July 2016

Who is funding the study?
Beijing Municipal Administration of Hospitals Clinical Medicine Development of Special Funding
(China)

Who is the main contact?
Professor Linpeng Wang
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
ZYLX201412

Study information

Scientific Title
Neuroplasticity changes on human motor cortex induced by acupuncture therapy for health subjects: a preliminary study

Study objectives
Bilateral excitability of primary motor cortex and interhemispheric interaction could be modulated by acupuncture intervention on healthy subject.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethical Committee of Beijing Hospital of Traditional Chinese Medicine, 24/03/2016, ref: 2016BL-018-001

Study design

Interventional single-centre randomised cross-over study

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Cortical neural plasticity

Interventions

Participants are randomised to receive two treatment periods in a random order. Between the treatment periods, there is a 7 day wash-out period where no treatment is received.

Intervention period: Participants receive a 30 minute period of acupuncture treatment, in which needles are applied to ten acupoints located on the left forearm, hand and lower leg are applied. The needling methods of "lifting and thrusting" and "rotating" are conducted on each point until the sensation of Deqi (a characteristic sensation of aching and tingling) is reported by the subjects. Then, the needles are kept in situ without further stimulation.

Control period: Participants are asked to sit comfortably on an armchair and are instructed to keep relaxed but alert during the control period. No needling stimulation takes place.

Transcranial magnetic stimulation measures, including resting motor threshold, amplitudes of motor evoked potential and interhemispheric inhibition are assessed before and 10 minutes after each treatment period.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Amplitudes of motor evoked potential on primary motor cortex are measured using the transcranial magnetic stimulation before and 10 minutes after each treatment period.

Key secondary outcome(s)

1. Resting motor threshold is measured using transcranial magnetic stimulation before and 10 minutes after each treatment period
2. Interhemispheric inhibition is measured using transcranial magnetic stimulation before and 10 minutes after each treatment period
3. F-wave is measured using electromyography before and 10 minutes after each treatment period

Completion date

31/07/2016

Eligibility

Key inclusion criteria

1. Without neurological, psychiatric or other medical problems
2. Right-handed
3. Aged 18-65 years

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Total final enrolment

10

Key exclusion criteria

Reported contra-indication to transcranial magnetic stimulation.

Date of first enrolment

02/05/2016

Date of final enrolment

24/07/2016

Locations**Countries of recruitment**

China

Study participating centre

Beijing Hospital of Traditional Chinese Medicine

Meishuguanhoujie No. 23

Dongcheng Province

Beijing

China

100010

Sponsor information

Organisation

Beijing Hospital of Traditional Chinese Medicine

ROR

<https://ror.org/057vq6e26>

Funder(s)

Funder type

Government

Funder Name

Beijing Municipal Administration of Hospitals Clinical Medicine Development of Special Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2017	27/11/2020	Yes	No