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

Submission date
24/01/2017

Recruitment status
No longer recruiting

Registration date
25/01/2017

Overall study status
Completed

Last Edited
27/11/2020

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

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

Secondary outcome measures
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

Overall study start date
01/12/2015

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
10

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

Sponsor details
Meishuguanhoujie no. 23
Dongcheng District
Beijing
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100010

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Planned publication in the journal Neural Plasticity before March 2017.

The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Linpeng Wang (wlp5558@sina.com)

Intention to publish date
01/03/2017

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