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Is pain relief from acupuncture reflected in the flow of blood-oxygen in the brain and muscles of migraine patients?

Submission date
27/10/2016

Recruitment status
No longer recruiting

Registration date
05/04/2017

Overall study status
Completed

Last Edited
11/08/2017

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Migraine is a debilitating headache condition which affects 15% of the population at least once in the course of a lifetime. Its causes are not well understood, but imbalances in blood flow in the brain are suspected to play a role. Acupuncture, originating from traditional Chinese medicine, is the practice of stimulating various points of the body, usually with needles, and has been found to be work well as part of preventive care for migraine and for pain relief from migraine attack. It has also been found to stimulate response from the brain, which has been observed by several measures, including changes in the blood flow. However, the connection with migraine is not yet well understood. To address this gap, this study is investigating whether pain relief from acupuncture is reflected in the flow of oxygenated blood in the brain and muscles. With a novel tool to record real-time changes in blood flow, namely by near-infrared spectroscopy (NIRS), it may be possible to see how successful the treatment is while the effect is being felt, as well as provide further clues into the causes of migraine.

Who can participate?
Adults aged 20-65 diagnosed with migraine

What does the study involve?
Participants are randomly allocated to one of three groups. Those in group 1 receive “true” (verum) acupuncture, meaning needling at specified points to achieve a specific feeling and effect. Those in group 2 receive “placebo” acupuncture, where the needling is applied more shallowly and at points not believed to have an effect. Participants in group 3 are not given acupuncture. The acupuncture treatments (groups 1 and 2) are compared by examining changes in the blood flow in the brain while receiving acupuncture, by using NIRS. There is also comparison among all three groups to assess the effect on migraine symptoms.

What are the possible benefits and risks of participating?
Participants may possibly benefit from an improvement of their migraine symptoms.

Acupuncture is considered safe for most patients, but some may have adverse reaction to contact with the (hypo-allergenic) needles, such as redness of the skin. Some participants may observe a worsening of their symptoms, before they see improvement.

Where is the study run from?
The study is run with the cooperation of China Medical University and Taiwan National University Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
August 2014 to July 2017

Who is funding the study
National Research Institute of Chinese Medicine (Taiwan)

Who is the main contact?
Dr Wei-Zen Sun
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
201402077RINA, version 17-Mar-2016; MOHW104-NRICM-C-114-000-005

Study information

Scientific Title
The analgesic modulation of standardized acupuncture and the cerebral and muscular hemodynamic response in migraine patients: a randomized, placebo-controlled trial

Study objectives
The analgesic effect of verum acupuncture is greater than that of placebo acupuncture, and that of placebo acupuncture exceeds that of no acupuncture. Furthermore, near-infrared

spectroscopy (NIRS) of the brain can provide sufficient detail to distinguish various clinical responses to needling of the scalp in real time, while the readings in the upper trapezius muscle are expected to behave as a control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. National Taiwan University Hospital Research Ethics Committee, 29/09/2014, ref: 201402077RINA (Version 05-Aug-2014)
2. The National Taiwan University Hospital Research Ethics Committee, 05/05/2016, ref: 201402077RINA (Version 17-Mar-2016)

Study design
Interventional randomized parallel placebo-controlled quasi double-blind multi-center study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Migraine (with or without aura)

Interventions
Participants are randomly allocated to one of the three groups below:

1. Verum acupuncture (de-qi-inducing needling at specified points)
2. Placebo acupuncture (shallow needle stimulation a specified distance away from specified points, no induction of de qi)
3. No acupuncture (patients receive no acupuncture in the study period)

In all arms, patients have access to medication prescribed prior to, including rescue medicine for headache. Acupuncture (verum or placebo) is administered three times a week for four weeks, with sessions lasting 30 minutes each.

Blood flow in the brain are compared for groups 2 and 3 using near-infrared spectroscopy.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Primary clinical measures:
1. Headache duration (headache hours/day)
2. Headache frequency (headache days/month) 3. Headache intensity (VAS score)

These are recorded in headache diaries covering the 12-week duration of the study and apply to all treatment arms

Primary hemodynamic measures:
1. Regional oxygenation of the cerebral cortex (Oxy/Deoxy-Hb ratio)
2. Regional oxygenation of the upper trapezius (Oxy/Deoxy-Hb ratio)

These are measured by near-infrared spectroscopy (NIRS) during each acupuncture treatment session and apply only to the two acupuncture arms, verum and placebo

Key secondary outcome(s))
1. Medications (name, type, usage), recorded in headache diary
2. Presence of migraine aura (Yes/No), noted by attending physician during treatment session
3. Headache intensity (VAS score), noted by attending physician during treatment session
4. Headache site (Left/Right), noted by attending physician during treatment session
5. Body movement (duration of movement per 10-min interval), recorded by video of treatment session

Except the measure for medications (#1), the above apply only to the acupuncture arms, verum and placebo.

Completion date
31/07/2017

Eligibility

Key inclusion criteria
1. Diagnosed with migraine (with or without aura, according to ICHD-II criteria)
2. Patient has given consent to receive acupuncture treatment
3. Age (20-65)
4. Patient has provided informed consent to participate (informed about possibility of receiving placebo treatment or no acupuncture treatment, informed about the use of NIRS during acupuncture sessions)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patient refuses acupuncture treatment
2. Patient has contra-indications for acupuncture
3. Patient suffers from hemophilia, skin infections or has other conditions that preclude the use of acupuncture
4. Suffers mental illness
5. Pregnant or lactating

6. Patient is currently participating in another clinical study or has participated in another clinical trial within 3 months to enrolling in the study
7. Patient opts or drops out of study
8. Patient has received acupuncture treatment within the past 3 months
9. Patient fails to follow the parameters of the study, such as number of acupuncture treatments per week

Date of first enrolment
01/08/2014

Date of final enrolment
31/07/2017

Locations

Countries of recruitment
Taiwan

Study participating centre
China Medical University
No.91, Hsueh-Shih Road
Taichung
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40402

Study participating centre
National Taiwan University Hospital
No.7, Chung Shan S. Rd.Zhongshan S. Rd)
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Sponsor information

Organisation
National Research Institute of Chinese Medicine, Ministry of Health and Welfare

ROR
https://ror.org/00nnyvd56

Funder(s)

Funder type
Government

Funder Name
National Research Institute of Chinese Medicine, Ministry of Health and Welfare

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Wei-Zen Sun (wzsun@ntu.edu.tw).

IPD sharing plan summary
Available on request