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

Submission date	Recruitment status	Prospectively registered
Pegistration date		Protocol Statistical analysis plan
05/04/2017	Completed	Results
Last Edited	Condition category	Individual participant data
11/08/2017	Nervous System Diseases	[_] 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 wzsun@ntu.edu.tw

## **Contact information**

**Type(s)** Scientific

**Contact name** Dr Wei-Zen Sun

#### **Contact details**

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## Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers 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)

 National Taiwan University Hospital Research Ethics Committee, 29/09/2014, ref: 201402077RINA (Version 05-Aug-2014)
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

**Secondary study design** Randomised parallel trial

Study setting(s) Hospital

#### Study type(s)

Treatment

**Participant information sheet** No participant information sheet available

#### 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 measure

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

#### Secondary outcome measures

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.

Overall study start date

01/08/2014

**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

#### Age group

Adult

**Sex** Both

Target number of participants

60

#### 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 Taiwan 40402

## Study participating centre

National Taiwan University Hospital No.7, Chung Shan S. Rd.Zhongshan S. Rd) Zhongzheng Dist Taipei Taiwan 10002

## Sponsor information

#### Organisation

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

#### Sponsor details

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#### Sponsor type

Government

#### 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**

Publication and dissemination plan

## Intention to publish date 31/07/2018

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