

# Evaluation of acupuncture efficacy for prophylaxis of migraine attacks - phase II trial

<b>Submission date</b> 17/03/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/06/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/06/2010	<b>Condition category</b> 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**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
90/2000

## Study information

## **Scientific Title**

### **Study objectives**

Acupuncture could be an option to prevent migraine attacks.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved by the Research Ethical Committee of the School of Medical Sciences, State University of Campinas (Unicamp) on 13/06/2000, reference number: 90/2000

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

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

Prevention

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Migraine

### **Interventions**

In the pilot study, patients were randomized into two different groups, real and sham acupuncture groups. Both groups received 16 sessions of acupuncture in three months. Eight sessions in the first month of the treatment period, four sessions in the second month of the treatment period and four sessions in the third month of the treatment period. The treatment group was treated with individualized acupuncture following the traditional Chinese principles. The control group received a sort of sham acupuncture called minimal acupuncture. The minimal acupuncture consisted of a very shallow needle insertion in the acupuncture points with the needle almost falling out.

### **Intervention Type**

Other

### **Phase**

Phase II

### **Primary outcome measure**

The percentage of patients with a greater than 50% reduction in their migraine attacks frequency in the second, third, fourth, fifth and sixth headache diaries compared with the first one (baseline period).

### **Secondary outcome measures**

1. The number of the migraine days per month
2. The percentage of patients with reduction  $\geq 40\%$  in migraine attacks frequency
3. Frequency of migraine attacks
4. Average duration of a migraine attack
5. Average headache severity
6. Total duration of migraine pain in hours per diary
7. Rate of rescue medication used
8. Nausea and vomiting frequency, all of them comparing the first diary (baseline period) with others headache diaries

### **Overall study start date**

07/12/2001

### **Completion date**

30/06/2003

## **Eligibility**

### **Key inclusion criteria**

1. Patients suffering from migraine with or without aura for at least one year were diagnosed according to criteria of the International Headache Society
2. Male or female, aged 18-50 years
3. Patients with only one type of headache (exclusively migraine)
4. Patients who had not used acupuncture or drugs with migraine prophylactic effects within the last three months
5. Patients who could come to the hospital for 17 times in the following twelve weeks (acupuncture evaluation and acupuncture treatment period)

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Upper age limit**

50 Years

### **Sex**

Both

### **Target number of participants**

37

**Key exclusion criteria**

Patients with any other chronic pain syndrome, who were misusing drugs or alcohol and who occasionally, used a minor tranquilizer or sedative.

**Date of first enrolment**

07/12/2001

**Date of final enrolment**

30/06/2003

**Locations****Countries of recruitment**

Brazil

**Study participating centre**

R Rafael Sampaio 428

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**Sponsor information****Organisation**

State of São Paulo Research Foundation (FAPESP) (Brazil)

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**Sponsor type**

Government

**ROR**

<https://ror.org/02ddkpn78>

**Funder(s)****Funder type**

Government

### Funder Name

State of São Paulo Research Foundation (FAPESP) (Brazil)

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### 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	01/02/2008		Yes	No