

# Evaluation of acupuncture efficacy for migraine attacks prophylaxis - a phase III 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**

Randomized 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**

The 67 patients were randomized into two different groups: real and sham acupuncture groups. Both groups were treated with 16 acupuncture sessions in twelve weeks. Eight in the first four weeks of the treatment period, seven in the next four weeks of the treatment period and one in the four weeks of the treatment period. Treatment was individualized in the real acupuncture group following the Traditional Chinese Medicine (TCM) principles and minimal acupuncture was used in the sham acupuncture group not respecting the TCM rules.

### **Intervention Type**

Other

### **Phase**

Phase III

### **Primary outcome measure**

The percentage of patients with a reduction of  $\geq 50\%$  in migraine attack frequency and the total of the migraine days compared with the baseline period.

**Secondary outcome measures**

1. The percentage of patients with a reduction of  $\geq 40\%$  in migraine attacks frequency
  2. Frequency of migraine attacks
  3. Average duration of a migraine attack
  4. Average headache severity
  5. Total duration of migraine pain in hours per diary
  6. Rate of rescue medication used
  7. Nausea and vomiting frequency
- All of them comparing the first diary (baseline period) with the other group's headache diaries.

**Overall study start date**

01/03/2003

**Completion date**

30/01/2005

**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**

67

**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**

01/03/2003

**Date of final enrolment**

30/01/2005

## **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**

## 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="#">Abstract results</a>	942-943	01/10/2005		No	No
<a href="#">Results article</a>		01/05/2006		Yes	No