

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

Submission date 17/03/2006	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 05/06/2006	Overall study status Completed	☐ Protocol
Last Edited 07/06/2010	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☒ Results
		☐ 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

Protocol serial number
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

Study type(s)

Prevention

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

50 years

Sex

All

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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Brazil
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Sponsor information

Organisation

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

ROR

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

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

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?
Results article		01/05/2006		Yes	No
Abstract results	942-943	01/10/2005		No	No