

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

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Prevention

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(s)

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).

Key secondary outcome(s))

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

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

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

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)

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	results	01/02/2008		Yes	No