ISRCTN74335441 https://doi.org/10.1186/ISRCTN74335441

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

Submission date	Recruitment status	[ ] Prospectively registered
17/03/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/06/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/06/2010	Nervous System Diseases	

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 differents 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 ≥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 ≥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

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