ISRCTN93327878 https://doi.org/10.1186/ISRCTN93327878

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

Submission date	Recruitment status
17/03/2006	No longer recruiting
Registration date	**Overall study status**
05/06/2006	Completed
Last Edited	**Condition category**
07/06/2010	Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] 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

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 ≥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?
Results article	results	01/02/2008		Yes	No