Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of acupuncture as an adjunct to Amitriptyline and Propranolol in migraine prophylaxis

Protocol summary

Study aim
To investigate whether acupuncture as an adjunct to amitriptyline and propranolol is more effective than use this two drugs alone for reducing headache frequency, nausea & vomiting frequency, intensity (PI-NRS) and duration of attack in 4 Stages?

Design
A prospective study was conducted in which 100 patient of both sexes and ages 18-60 years old with migraine were randomly assigned to two groups, group A received amitriptyline(25 mg / day) and propranolol (20 mg twice daily) for migraine prophylaxis, and group B received drugs + acupuncture. Clinical trial with the control group, pragmatic, community based and parallel group

Settings and conduct
Patients before the start of the study, after 4 weeks, at the end of the study and 4 weeks after the completion of the study, recorded the number and severity (based on PI-NRS) and the duration of their migraine attacks, and a questionnaire given to them Filled up.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1.People with migraine (according to IHS) that age between 18 to 60 2.number of attack more than 4 along 4 weeks 3.The patient’s tendency to participate in the study Exclusion criteria: 1.Other kinds of headache 2.Taking another drugs for migraine prophylaxis 3.Pregnancy and lactation 4.Depression or Parkinsonism 5.Hypersensitivity to drugs 6.Tendency to quit of study

Intervention groups
A prospective study was conducted in which 100 patient of both sexes and ages 18-60 years old with migraine were randomly assigned to two groups, group A received amitriptyline(25 mg / day) and propranolol (20 mg twice daily) for migraine prophylaxis, and group B received drugs + acupuncture.

Main outcome variables
The effect of acupuncture on the prevention of migraine attacks, the duration of attacks, the number of nausea and vomiting and severity of attacks

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160813029327N17**
Registration date: **2018-09-24, 1397/07/02**
Registration timing: **retrospective**

Last update: **2018-09-24, 1397/07/02**
Update count: **0**

Registration date
2018-09-24, 1397/07/02

Registrant information

Name
Ramin Abrishami

Name of organization / entity
Islamic Azad University, Pharamceutical sciences branch

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
no sonsor usd

Expected recruitment start date
2017-06-22, 1396/04/01

Expected recruitment end date
2018-03-21, 1397/01/01

Actual recruitment start date
2017-07-06, 1396/04/15

Actual recruitment end date
2018-04-30, 1397/02/10
Trial completion date
2018-04-30, 1397/02/10

Scientific title
The effect of acupuncture as an adjunct to Amitriptyline and Propranolol in migraine prophylaxis

Public title
The effect of acupuncture in migraine prophylaxis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
People with migraine that age between 18 to 60 Number of attack more than 4 along 4 week The patient’s tendency to participate in the study
Exclusion criteria:
Other kinds of headache like tension headache and ... . Taking another drugs for migraine prophylaxis Pregnancy and Lactation Depression or Parkinsonism Tendency to quit of study Hypersensitivity to medication treatment
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **100**
More than 1 sample in each individual
Number of samples in each individual: **4**
Severity of attacks according to PI-NRS in 4 stages (baseline, after 4 weeks, after 6 weeks and after 4 weeks from the end)
Actual sample size reached: **100**
More than 1 sample in each individual
Actual sample size in each individual: **4**
Severity of attacks according to PI-NRS in 4 stages (baseline, after 4 weeks, after 6 weeks and after 4 weeks from the end)
Randomization (investigator's opinion)
Randomized
Randomization description
Random number table: based on Random Sequence Generator via random.org website two groups were made. Patients were allocated in one of two groups based on their entry sequence.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University of Pharmaceutical Sciences
Street address
Gholhak street, Shariati street
City
tehran
Province
Tehran
Postal code
1941933111
Approval date
2017-08-27, 1396/06/05
Ethics committee reference number
IR.IAU.PS.REC.1396.114

Health conditions studied

1

Description of health condition studied
migraine
ICD-10 code
G43.9
ICD-10 code description
Migraine, unspecified

Primary outcomes

1

Description
The average number of migraine attacks
Timepoint
4 weeks before the start of the study, after 4 weeks, at the end of the study and 4 weeks after completion of the study
Method of measurement
Questionnaire

2

Description
Intensity
Timepoint
4 weeks before the start of the study, after 4 weeks, at the end of the study and 4 weeks after completion of the study
Method of measurement
Pain intensity questionnaire based on Pain Intensity Numerical Rate Scale

3

Description
Duration of attacks
Timepoint
4 weeks before the start of the study, after 4 weeks, at the end of the study and 4 weeks after completion of the study
Method of measurement
Questionnaire

4

Description
Nausea and Vomiting frequency
Timepoint
4 weeks before the start of the study, after 4 weeks, at the end of the study and 4 weeks after completion of the study
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The first group (control) received 25 mg amitriptyline at night and 20 mg propranolol twice daily for migraine prophylaxis.
Category
Prevention

2

Description
The second group (intervention) received 25 mg amitriptyline at night and 20 mg propranolol twice a day for acupuncture as well as prophylaxis. (acupuncture consist 12 sessions per patient and 2 sessions per week)
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Booali hospital
Full name of responsible person
Atena Mahdavi nasab
Street address
Booali hospital, Imam Hossein Square., Damavand Ave.,
City
Tehran
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Tehran
Postal code
17117
Phone
+98 21 3334 8036
Email
booali.hospital96@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Farshad Hashemian
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Yakhchal Ave., Shariati street.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad Univercity of Pharmaceutical Sciences
Full name of responsible person
Ramin Abrishami
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Unidentified dermographic and variables will be shared.
When the data will become available and for how long
After publication up to three years
To whom data/document is available
Academics
Under which criteria data/document could be used
Academic and/or clinical use
From where data/document is obtainable
Via email to corresponding author
What processes are involved for a request to access data/document
After assurance about academic background
Comments