

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+98 21 2264 1889

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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

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Province

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

Street address

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 University 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 scientific inquiries

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Person responsible for updating data

Contact

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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 demographic 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