# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

02 Jun 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

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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.,
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17117
**Phone**
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**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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r_abrishami@iaups.ac.ir
**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.
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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**