Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The comparison of treatment effect between acupuncture and botox injection effects on prevention of chronic migraine among patients referred to pain clinic of Poursina hospital in 2014

Protocol summary

Summary

In this study we compare the therapeutic outcome of two method acupuncture and botox injection in prevention of chronic migraine, the probable benefits and disadvantages of these methods is measured and used of them to true conduct the patient to select the best method in prevention of chronic migraine. Include criteria: the patient with chronic migraine (IHS criteria) that have 20 to 60 years old. The exclusion criteria: the other migraine reasons, pregnant women, psychotic disorder or mental retardation, epilepsy, history of neurologic disorder heart disease and trauma, arterial hypertension and non tendency for being in study. In this study the patient suffering chronic migraine that received the prophylaxis treatment for more than 3 months and had no betterment in migraine symptoms based on their tendency select one of acupuncture or botox injection. Total number of patients is 100 people, 50 people in each group. In this study intervention is one part of patient treatment and we don't new intervention. Primary outcome is reduction in severity and days of headache and improvement in life quality.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404146186N3**
Registration date: **2014-04-30, 1393/02/10**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-04-30, 1393/02/10

Registrant information

Name

Bahram Naderi Nabi

Name of organization / entity

Guilan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2014-05-05, 1393/02/15

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of treatment effect between acupuncture and botox injection effects on prevention of chronic migraine among patients referred to pain clinic of Poursina hospital in 2014

Public title

Comparison of acupuncture and botox in prevention of chronic migraine

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:the patient aged 20 to 60 years old that

have chronic migraine (with HIS criteria) that come to Rasht poursina hospital pain clinic in 2014. Exclusion criteria: other reasons of headache such as brain tumor; the people that have other headache addition to migraine; pregnant women; psychotic disorder or mental retardation, epilepsy; history of neurological disorder, heart disease and trauma, arterial hypertension; patient dissatisfaction to enter in the study.

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Vice chancellor for research of Guilan University of Medical Sciences

Street address
Shahid Beheshti Hiway

City
Rasht

Postal code

Approval date
2014-02-22, 1392/12/03

Ethics committee reference number
1920422818

Health conditions studied

1

Description of health condition studied
Migraine

ICD-10 code
G43

ICD-10 code description
Migraine

Primary outcomes

1

Description
Pain intensity

Timepoint
Referral time, the end of first month, end of second month and the end of third month

Method of measurement
VAS score

Secondary outcomes

1

Description
Frecuancy of headache in month

Timepoint
Referral time,the end of first month, end of second month and the end of third month

Method of measurement
Incidence number of migraine headache with IHS

Intervention groups

1

Description
Intervention1: Botox, 155 unit Botulinum toxin XEOMIN, GERMANY, Merz Group Services GmbH, in one time injection

Category
Treatment - Drugs

2

Description
Intervention 2: Acupuncture, every other day up to 15 times in two period , one week interval, along 70 days from initial of treatment

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Porsina hospital pain clinic

Full name of responsible person
Dr Bahram Naderi Nabi

Street address
Namjoo Avenue

City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor of Guilan University of Medical Sciences
Full name of responsible person
Abtin Heidarzadeh
Street address
Shahid beheshti Highway
City
rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor of Guilan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty