

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 methods: acupuncture and botox injection in prevention of chronic migraine. The probable benefits and disadvantages of these methods are measured and used to guide the patient to select the best method in prevention of chronic migraine. Inclusion criteria: the patient with chronic migraine (IHS criteria) that is 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 from chronic migraine that received prophylaxis treatment for more than 3 months and had no betterment in migraine symptoms based on their tendency to 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 do not have a 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3323 4600

##### Email address

naderi\_bahram@gums.ac.ir

##### 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 Porsina 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

### Contact

**Name of organization / entity**

Guilan University of Medical Sciences

**Full name of responsible person**

Dr Bahram Naderi Nabi

**Position**

Assosiate professor /Anesthesiologist

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## Person responsible for scientific

## inquiries

### Contact

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## Person responsible for updating data

### Contact

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Assosiate professor of Guilan university of medical sciences

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**City**

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**Fax****Email****Web page address**

## 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*