Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of botulinum toxin a in patients with migraine headaches and treatment-resistant tension in people aged 20 to 70 years

Protocol summary

Study aim
Determining the effect of botulinum toxin A in patients with treatment-resistant migraine and tension headaches in individuals aged 20 to 70 years

Design
Phase 3 clinical trial study without a control group with two parallel groups without blinding on 50 patients divided into two groups of 25 people receiving standard medication

Settings and conduct
We do the work in the city of Qom. We have two groups of patients for injection. One group of patients with treatment-resistant tension and one group of patients with treatment-resistant migraine. It is done with an insulin syringe and subcutaneously and in the injection areas according to the preempt protocol in migraine patients and dispersion and spasm of painful areas in tension patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients aged 20 to 70 years with treatment-resistant migraine and tension headaches
Exclusion criteria: Age less than 20 and more than 70 years old, presence of neuromuscular diseases, and pregnancy

Intervention groups
We will have two intervention groups: one group of people with treatment-resistant tension headaches and one group of people with treatment-resistant migraine headaches. We will inject each group with the drug and then evaluate them over a period of 3 months

Main outcome variables
Change in frequency (number of headaches per week) ; severity (via VAS scale) ; headache duration (in hours) ; change in quality of life (with WHO questionnaire)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250308064974N1**
Registration date: **2025-09-29, 1404/07/07**
Registration timing: **prospective**

Last update: **2025-09-29, 1404/07/07**
Update count: **0**

Registration date
2025-09-29, 1404/07/07

Registrant information

Name
Fatemeh Tabrizi

Name of organization / entity

Country
Iran (Islamic Republic of)

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tabrizi223@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-23, 1404/08/01

Expected recruitment end date
2025-12-22, 1404/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of botulinum toxin a in patients with migraine headaches and treatment-resistant tension in people aged 20 to 70 years

Public title
Comparison of the effect of botulinum toxin a in patients with migraine headaches and treatment-resistant tension in people aged 20 to 70 in patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients aged 20 to 70 years Patients with treatment-resistant migraine headache Patients with treatment-resistant tesion headache
Exclusion criteria:
Age less than 20 and more than 70 years
Age
From **20 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qom University of Medical Sciences
Street address
No. 83, (Alley No. 4), Shahid Lotfi Niasar, Jihad Daneshgahi Alley, Safashar Street, Qom
City
Qom
Province
Ghoum
Postal code
93456-37169
Approval date
2025-08-19, 1404/05/28
Ethics committee reference number
IR.MUQ.REC.1404.126

Health conditions studied

1

Description of health condition studied
Migrain and tension headache
ICD-10 code
G43
ICD-10 code description
Migraine

Primary outcomes

1

Description
Pain
Timepoint
4 ,8 ,12 weaks after injection
Method of measurement
The Visual Analogue Scale

Secondary outcomes

1

Description
Time of pain
Timepoint
4 ,8 ,12 week after injection
Method of measurement
Time if headache (hours)

2

Description
Number of headache attacks per week
Timepoint
4, 8 ,12 weeks after injection
Method of measurement
Number of headache attacks per week

Intervention groups

1

Description
First Intervention groupPatients with treatment-resistant chronic migraine headaches are in the first intervention group, receiving botulinum toxin type A subcutaneously with a fine insulin needle according to the preempt protocol.
Category
Treatment - Drugs

2

Description
Intervention group: Patients with treatment-resistant chronic tension headaches are in the second intervention group, who receive botulinum toxin type A subcutaneously with a fine insulin needle in the frontal,

temporal, and occipital regions.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid beheshti hospital

Full name of responsible person
Fateme Tabrizi

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Beheshti Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ghoum University of Medical Sciences

Full name of responsible person
Mohammad Aghaali

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Safashar Street

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dr.aghaali@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Ghoum University of Medical Sciences

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
Ghoum University of Medical Sciences

Full name of responsible person
Fateme Tabrizi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Neurology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to the existence of personal information of patients and in order to protect privacy and observe medical ethics in maintaining patient confidentiality
Study Protocol
No - There is not 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
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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