Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effects of Botox and rTMS on reducing migraine symptoms

Protocol summary

Study aim
Comparison of the effects of Botox and rTMS on reducing migraine symptoms
Design
Clinical trial with two intervention groups, with parallel groups, without blinding, non-randomized, phase 3 on 100 patients.
Settings and conduct
Botox: Botox 500 units are injected into specific areas of the head and neck over a period of 3 months according to standard FDA protocol. rTMS is a high-frequency (10-20 Hz) repetitive transcranial magnetic stimulation device that is used to stimulate the motor cortex. 15-20 sessions, each session lasting 20 minutes, will be administered over a period of 3 months.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 25 to 55 years Suffering from migraine Exclusion criteria: Pregnant or lactating women Suffering from brain tumors Patients with metal implants in the head and neck Sensitivity to Botox
Intervention groups
Group 1: Received Botox treatment. Group 2: Received repetitive transcranial magnetic stimulation (rTMS) treatment.
Main outcome variables
Change in the number of migraine attacks

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20251022067727N1**
Registration date: **2025-11-26, 1404/09/05**
Registration timing: **prospective**

Last update: **2025-11-26, 1404/09/05**
Update count: **0**
Registration date
2025-11-26, 1404/09/05

Registrant information
Name
Mehrnoosh Ghaneifar
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-12-21, 1404/09/30
Expected recruitment end date
2026-03-21, 1405/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effects of Botox and rTMS on reducing migraine symptoms

Public title
Comparing the effects of Botox and rTMS on reducing migraine symptoms
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age 25 to 55 years Suffering from migraine
Exclusion criteria:
Pregnant or lactating women Suffering from brain tumors Patients with metal implants in the head and neck Sensitivity to Botox
Age

From **25 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not 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

Ethics Committee of Tehran Islamic Azad University of Medical Sciences

Street address

Headquarters Building of Tehran Islamic Azad University of Medical Sciences, Corner of Gol Yakh St, Ayane Blvd, Amir Pabarja St, Golhak Road, Dr. Shariati St, Tehran

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1949635881

Approval date

2025-09-01, 1404/06/10

Ethics committee reference number

IR.IAU.TMU.REC.1404.254

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

Change in the number of migraine attacks

Timepoint

Before treatment, one, three and six months after treatment

Method of measurement

Interview and taking a history

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Botox injections of 500 units are performed over a period of 3 months at specific points on the head and neck according to standard FDA protocol.

Category

Treatment - Drugs

2

Description

Intervention group: rTMS is a magnetic stimulation technique that uses a high-frequency (10-20 Hz) repetitive magnetic stimulation device to stimulate the motor cortex. 15-20 sessions, each treatment session lasting 20 minutes, will be performed for 3 months.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Farhikhtegan Hospital, Tehran

Full name of responsible person

Mehrnoush Ghaneifar

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Masoud Parsania
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Headquarters Building of Tehran Islamic Azad University of Medical Sciences, Corner of Gol Yakh St, Ayane Blvd, Amir Pabarja St, Golhak Road, Dr. Shariati St, Tehran
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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
Full name of responsible person
Mehrnoush Ghaneifar
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Student
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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
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available