

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A randomized clinical trial for comparison of two methods of BOTOX injection (FTP & FSFD) to improve headache frequency & quality of life of migrainous headache patients

Protocol summary

Study aim

Help to improve of quality of life of chronic migraine headache patients & lowering of complications & treatment cost

Design

Single popular based clinical trial

Settings and conduct

40 patients who their ages between 18 to 65 that referred & documented by neurologist of Ali ebne Abitaleb hospital divided to two groups then each one injected by one of mentioned method & follow them base on diary migraine chart & life style questionnaire at days 0, 30, 60, 90 & 120.

Participants/Inclusion and exclusion criteria

Inclusion criteria : all patients 18 to 65 years old with chronic migraine that suffering at least 4 hours of each days & for 15 days or more of month. Exclusion criteria: pregnancy, drug sensivity, coagulopathy, infection of injection site, history of previous treatment with BOTOX, complicated migraine, Beck severity scale point more than 24, secondary migraine due to other reasons, psychologic disorders, neuromuscular junction disorders

Intervention groups

All patients 18 to 65 years old with chronic migraine that suffering at least 4 hours of each days & for 15 days or more of month.

Main outcome variables

Decrease of frequency & severity of migrainous headache & improvement of quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180203038600N1**

Registration date: **2019-04-09, 1398/01/20**

Registration timing: **retrospective**

Last update: **2019-04-09, 1398/01/20**

Update count: **0**

Registration date

2019-04-09, 1398/01/20

Registrant information

Name

Mohadese Fekri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3433 9042

Email address

fekri.mhds@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-08, 1396/11/19

Expected recruitment end date

2018-04-07, 1397/01/18

Actual recruitment start date

2018-02-08, 1396/11/19

Actual recruitment end date

2018-04-07, 1397/01/18

Trial completion date

2018-07-19, 1397/04/28

Scientific title

A randomized clinical trial for comparison of two methods of BOTOX injection (FTP & FSFD) to improve headache frequency & quality of life of migrainous headache patients

Public title

Comparison of two methods of BOTOX injection (FTP & FSFD) to improve of chronic migrainous headache patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have at least 15 days headache that maintain for 4 hour or more Patients who had no improvement in severity & frequency of headaches by using prophylactic drug agents like that Beta blockers, CCB, anti convulsive drugs & anti depressant

Exclusion criteria:

Pregnancy History of BOTOX injection or other Botulinum serotypes Neuromuscular junction disease Psychologic disorders that have negative impact on clinical trial Beck severity scale of depression more than 24 Primary or secondary headaches due to another reasons Complicated migraine Drug sensivity Coagulopathy Infection of injection skin site

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **18**

Randomization (investigator's opinion)

Randomized

Randomization description

randomization as simple randomized & individualization with using of locked pockets that data bases is hiding from neurologist who visits & evaluates patients & statistical consultant will analyses data bases, too.

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 Rafsanjan university of medical science

Street address

Rafsanjan university of medical science, Imam Ali Blvd., Ali ebne Abi taleb square, Rafsanjan Town

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2017-12-26, 1396/10/05

Ethics committee reference number

IR.rums.rec.1396.151

Health conditions studied

1

Description of health condition studied

chronic migraine

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura [common migraine]

Primary outcomes

1

Description

Frequency of migraine headache attacks

Timepoint

The days 0, 30, 60, 90, 120 after injection

Method of measurement

Migraine diary chart

Secondary outcomes

1

Description

Quality of life improvement

Timepoint

Synchronous to first variable outcome evaluation

Method of measurement

Quality of life questionnaire approved by WHO

Intervention groups

1

Description

BOTOX injection for chronic migraine headache patients by FTP method

Category

Treatment - Drugs

2

Description

Intervention group: BOTOX injection for chronic migraine headache patients by FSFD method

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ebne Abitaleb hospital

Full name of responsible person

Dr.Salehi Hossein

Street address

Ali ebne Abitaleb hospital, Imam Ali Blvd., Ali ebne Abitaleb square, Rafsanjan Town

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr.shamsi Ali

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Fax**Email**

alishamsy@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rafsanjan 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**

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr.Fekri Mohadese

Position

Intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Position

Assistant Professor

Latest degree

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plastic surgery

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Person responsible for updating data

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Latest degree

Medical doctor

Other areas of specialty/work

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All documents reveal based on approved international
diary migraine chart & life style questionnaire.

When the data will become available and for how long

We can publish all result 6 month after data collection &
analysis.

To whom data/document is available

All physicians & researchers can use data for research &
treatment.

Under which criteria data/document could be used

All physicians & researchers can use data for research &
treatment.

From where data/document is obtainable

they can contact with this E-mail :
fekri.mhds@gmail.com.

What processes are involved for a request to access data/document

Job & reasons of user

Comments