

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Serum level of fibroblast growth factor 21 evaluation in patients with migraine headache treated by sodium valproate

Protocol summary

Study aim

Evaluation of serum levels of FGF-21 correlation with severity of headache and therapeutic response to sodium valproate in patients with migraine headache

Design

Prospective and open label clinical trial on 40 patients with migraine who candidate sodium valproate treatment.

Settings and conduct

Patients who referred to neurology clinic of Ibne Sina hospital with migraine headache diagnosis who candidate sodium valproate prophylaxis will be included. At baseline and end of the study period, the level of FGF-21, headache severity and treatment response according MIDAS evaluation will be recorded.

Participants/Inclusion and exclusion criteria

Adult patients were aged more than 18 years with recently migraine headache (with or without aura) diagnosis and candidate receiving sodium valproate will be included. exclusion criteria: other headache except migraine type, pregnancy, lactation, liver and kidney disease

Intervention groups

Adult patients are aged more than 18 years with recently migraine headache diagnosis (with or without aura) and candidate receiving therapeutic regimen of sodium valproate (1000 mg)

Main outcome variables

FGF-21serum level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190804044429N3**

Registration date: **2020-10-07, 1399/07/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-07, 1399/07/16**

Update count: **0**

Registration date

2020-10-07, 1399/07/16

Registrant information

Name

Monireh Ghazaeian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8863 6864

Email address

ghazaeianm@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-04, 1399/01/16

Expected recruitment end date

2021-04-05, 1400/01/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Serum level of fibroblast growth factor 21 evaluation in patients with migraine headache treated by sodium valproate

Public title

fibroblast growth factor 21 in migraine headache

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with recently migraine headache (with or without aura) candidate receiving prophylaxis regimen with sodium valproate

Exclusion criteria:
Headache sub-types other than migraine Pregnancy
Breast feeding Renal and Liver dysfunction

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **2**
From each patients, two blood samples will be given for FGF-21 serum levels, liver enzymes and cell blood counts analysis

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

Mazandaran University of Medical Science

Street address

Ibn Sina Hospital, Pasdaran Blvd

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2020-04-02, 1399/01/14

Ethics committee reference number

IR.MAZUMS.REC.1399.034

Health conditions studied

1

Description of health condition studied

Migrain

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

FGF-21 serum levels

Timepoint

on 0 and 48 days of the study

Method of measurement

Elisa kite

2

Description

Headache severity

Timepoint

On 0 and 48 days of the study

Method of measurement

VAS scale

Secondary outcomes

1

Description

Clinical response evaluation

Timepoint

On 0 and 48 days of the study

Method of measurement

MIDAS questionnaire

2

Description

side effects profile

Timepoint

weekly

Method of measurement

history taking

Intervention groups

1

Description

Intervention group: Sodium valproate 500 mg every 12 hours (1000 mg daily) for 12 weeks

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn Sina hospital

Full name of responsible person

Monireh Ghazaeian

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Ibn Sina hospital, Pasdaran Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

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Vice Chancellor for Research, Mazandaran University of Medical Sciences, Joybar 3way

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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

Mazandaran 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**

Mazandaran University of Medical Sciences

Full name of responsible person

Monireh Ghazaeian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Clinical Pharmacit

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results of trial including analysis data and method of the study

When the data will become available and for how long

At the time of publication, the data of the study will be available.

To whom data/document is available

Academic researchers, medical team and scientific institutes

Under which criteria data/document could be used

For research and practical purposes

From where data/document is obtainable

Dr. Monireh Ghazaeian, Faculty of pharmacy, Mazandaran University of Medical Sciences

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

The scientific responsible person of the study will reply to the request within 10 days.

Comments