Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 ware 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
Street address
Ibn Sina hospital, Pasdaran Blvd
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3334 3011
Email
ghazaeianm@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Majid Saeedi
Street address
Vice Chancellor for Research, Mazandaran University of Medical Sciences, Joybar 3way
City
Sari
Province
Mazandaran
Postal code
48157-33971
Phone
+98 11 3448 4800
Email
majsaeedi@gmail.com

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
Street address
Ibn Sina hospital, Pasdaran Blvd
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3334 3011
Email
ghazaeianm@gmail.com

Person responsible for scientific 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 pharmacy
Street address
Ibn Sina hospital, Pasdaran Blvd
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3334 3011
Email
ghazaeianm@gmail.com

Person responsible for updating data

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 pharmacy
Street address
Ibn Sina hospital, Pasdaran Blvd
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3334 3011
Email
ghazaeianm@gmail.com

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