Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Assessing the effect of zinc supplementation on lipid profile, hs-CRP, the frequency of migraine attacks and it`s duration and severity in adult women

Protocol summary

Study aim

Effect of zinc gluconate supplementation on serum hs-CRP, lipid profile, frequency of migraine attacks and its severity and duration in adult women

Design

A parallel double-blind randomized clinical trial (both patients and researchers). Randomization was performed using computer-generated random numbers.

Settings and conduct

Sample size and population: 60 women with migraine headache were selected and referred to the neurology clinic of Imam Khomeini Medical Center affiliated to Urmia University of Medical Sciences, Urmia, Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-55 years old, female, resident of Urmia, having episodic or chronic migraines, interested in participating in the exclusion criteria: using any supplement in the last 3 months, pregnancy, lactation, smoking 2 years history of head and neck surgery, history of vasculitis, malignancies, AIDS, history of diabetes and stroke, cardiovascular disease, asthma, rheumatoid arthritis, liver and kidney failure, kidney stones, lipid profile lowering drugs, medication use Nonsteroidal anti-inflammatory, history of mental disorders, hypertension, gastrointestinal diseases, lupus

Intervention groups

Patients were divided into two groups to receive 15 mg zinc gluconate (intervention group: n = 30) and placebo (control group: n = 30). Fasting blood samples were taken at baseline and 12 weeks after the intervention to determine serum zinc, lipid profile and hs-CRP. Intervention time: 12 weeks

Main outcome variables

Frequency, severity and duration of migraine attacks (primary outcome) Serum levels of zinc, cholesterol, triglycerides, LDL, HDL and hs-CRP (secondary outcome)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191014045100N1**
Registration date: **2020-02-18, 1398/11/29**
Registration timing: **retrospective**

Last update: **2020-02-18, 1398/11/29**
Update count: **0**

Registration date

2020-02-18, 1398/11/29

Registrant information

Name

monireh mazaheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4222 2893

Email address

mazaheri.m@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-06-20, 1398/03/30

Actual recruitment start date

2019-03-21, 1398/01/01

Actual recruitment end date

2019-08-16, 1398/05/25

Trial completion date

2019-11-21, 1398/08/30

Scientific title
Assessing the effect of zinc supplementation on lipid profile, hs-CRP, the frequency of migraine attacks and it`s duration and severity in adult women

Public title
Effect of supplementation on the treatment of migraine headaches

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age range 18-55 years female Resident of Urmia Having episodic or chronic migraines Interested in collaborating in the study with a 3-month intervention

Exclusion criteria:
Use of any supplement or multivitamin - mineral in the last 3 months Pregnancy Breastfeeding smoking History of serious head trauma or head and neck surgery in the past 2 years A history of vasculitis Malignancies AIDS History of diabetes History of stroke and coronary artery disease Cardiovascular disease Asthma Rheumatoid Arthritis Kidney or liver failure kidney stone Use of drugs that decrease lipid profile (total cholesterol, TG, LDL-C) Taking non-steroidal anti-inflammatory drugs such as ibuprofen and naproxen (for more than 15 days per month in the last 3 months) History of mental disorders such as depression blood pressure Digestive diseases 21. Lupus

Age
From **18 years** old to **55 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Actual sample size reached: **61**

Randomization (investigator's opinion)
Randomized

Randomization description
At the beginning of the study, participants were randomly divided into two groups of 30 intervention and placebo with 1: 1 allocation ratio. Random block method was used for this purpose and the random numbers required for this method were generated using RAS software. Random-sized blocks of 4 and 6 were used to keep the study blind. Random numbers were generated by the project statistical consultant.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and either the researchers or the evaluators of the outcome were unaware of the allocation of study groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Urmia University of Medical Sciences

Street address
Urmia, Apadana intersection, Zaker street, Bostan dormitory

City
urmia

Province
West Azarbaijan

Postal code
6257757168

Approval date
2019-04-28, 1398/02/08

Ethics committee reference number
IR.UMSU.REC.1398.045

Health conditions studied

1

Description of health condition studied
Migraine

ICD-10 code
G43

ICD-10 code description
Migraine

Primary outcomes

1

Description
Frequency of migraine attacks

Timepoint
At baseline (before intervention) and 30, 60, and 90 days after starting zinc gluconate supplementation

Method of measurement
Monthly Notepad

2

Description
The severity of migraine attacks

Timepoint
At baseline (before intervention) and 30, 60 and 90 days after zinc gluconate supplementation

Method of measurement
Pain severity questionnaire NRS (Numeric Rating Scale)

3

Description
The period of migraine attacks
Timepoint
At baseline (before intervention) and 30, 60 and 90 days after zinc gluconate supplementation
Method of measurement
Monthly Notepad

Secondary outcomes

1

Description
serum level of zinc
Timepoint
At baseline (before intervention) and 90 days after zinc gluconate supplementation
Method of measurement
dialab kit of zinc

2

Description
Serum cholesterol level
Timepoint
At baseline (before intervention) and 90 days after zinc gluconate supplementation
Method of measurement
pars azmun kit

3

Description
Serum triglyceride levels
Timepoint
At baseline (before intervention) and 90 days after zinc gluconate supplementation
Method of measurement
pars azmun kit

4

Description
serum level of Low Density Lipoprotein (LDL)
Timepoint
At baseline (before intervention) and 90 days after zinc gluconate supplementation
Method of measurement
pars azmun kit

5

Description
serum level of High Density Lipoprotein (HDL)
Timepoint
At baseline (before intervention) and 90 days after zinc gluconate supplementation
Method of measurement
pars azmun kit

6

Description
serum level of high sensitivity C-Reactive Protein (hs-CRP)
Timepoint
At baseline (before intervention) and 90 days after zinc gluconate supplementation
Method of measurement
pars azmun kit

Intervention groups

1

Description
Intervention group: Zinc Gluconate tablets, 15 mg, daily, orally for 12 weeks
Category
Treatment - Drugs

2

Description
Intervention group: Placebo tablets, 15 mg, daily, orally for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Monireh Mazaheri
Street address
Urmia, Apadana intersection, Zaker street, Bostan dormitory
City
Urmia
Province
West Azarbaijan
Postal code
6257757168
Phone
+98 44 3346 9935
Email
mazaheri.m@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Rasoul Zarrin
Street address

Urmia, Imam Reza Street, 12 meters, No. 56

City
Urmia

Province
West Azarbaijan

Postal code
6257757168

Phone
+98 44 3346 9935

Email
rasoul.zarrin@uqconnect.edu.au

Grant name

Grant code / Reference number

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

Title of funding source
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Rasoul Zarrin

Position
Faculty member

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Urmia St., Imam Reza Street, 12 meters south of No. 56

City
Urmia

Province
West Azarbaijan

Postal code
6257757168

Phone
+98 44 3346 9935

Email
rasoul.zarrin@uqconnect.edu.au

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Rasoul Zarrin

Position
Faculty member

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Urmia St., Imam Reza Street, 12 meters south of No. 56

City
Urmia

Province
West Azarbaijan

Postal code
6257757168

Phone
+98 44 3346 9935

Email
rasoul.zarrin@uqconnect.edu.au

Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Monireh Mazaheri

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

Street address
Bostan dormitory, urmia

City
Urmia

Province
West Azarbaijan

Postal code
6257757168

Phone
+98 31 4222 2893

Fax

Email
mazaheri.m@umsu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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

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