

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Oct 2020

Effect of zinc supplementation on symptoms among patients with migraine in comparison with placebo

Protocol summary

Study aim

Effect of zinc supplementation on symptoms of headache in patients with migraine

Design

Design: we will enroll 80 eligible patients with migraine aged 20- 60 years that will randomly be assigned into treatment and placebo groups.

Settings and conduct

Setting and conduct: The present study is a double blind method and the care provider, investigator, outcome assessor, data analyzer will not be aware of assigned interventions. Samples are patients with migraine that will be recruited from Imam Mousa Sadr Clinic and Ali Asghar Clinic. The participants will randomly assigned into treatment and placebo groups to receive Zinc supplementation or placebo tablets for 8 weeks.

Participants/Inclusion and exclusion criteria

Major inclusion criteria: aged 20-60 years; confirmation of migraine by neurologist; desire to participate in present study; do not use of oral contraceptive pill and lack of tension headaches. Major exclusion criteria: having chronic medical diseases; use of supplements containing (Zn, vitamin E, vitamin C, Selenium and Beta-carotene)

Intervention groups

Intervention group will receive supplementation of zinc sulfate (220 mg per day including 50 mg of elemental zinc, Alhavi Company) for 8- weeks and subjects in the other group will receive placebo (made at the School of Pharmacy, Isfahan University of Medical Sciences) during 8 weeks.

Main outcome variables

outcome measures variables: Migraine symptoms (severity , frequency and average duration of migraine attacks).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121216011763N23**
Registration date: **2018-01-16, 1396/10/26**
Registration timing: **retrospective**

Last update: **2018-01-16, 1396/10/26**

Update count: **0**

Registration date

2018-01-16, 1396/10/26

Registrant information

Name

Gholamreza Askari

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2110

Email address

askari@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

University of Medical Sciences is responsible for all costs

Expected recruitment start date

2016-02-01, 1394/11/12

Expected recruitment end date

2016-04-01, 1395/01/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of zinc supplementation on symptoms among

patients with migraine in comparison with placebo

Public title

Effect of Zinc supplementation on symptoms of migraine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

aged 20-60 years; confirmation of migraine by neurologist; desire to participate in present study; do not use of oral contraceptive pill, lack of tension headaches.

Exclusion criteria:

having chronic medical diseases; use of supplements containing Zn, vitamin E, vitamin C, Selenium and Beta-carotene

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In present study, simple randomization method will be used. The randomization unit is individually and we will use the random number table method for random sequences. A random numbered table is a collection of numbers that are without a specific pattern, completely random and as table. The next step is allocation concealment and will use sequentially numbered, sealed, opaque envelopes. Then, based on the sample size, number of envelopes with aluminum surface are provided and each random sequence created on a card and the cards are inserted into the envelopes, respectively. At the time of registration for the participants, according to eligible participants, one of the envelopes is opened and the allocated group for participants is revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Supplementation zinc and placebo will be packed in capsules that are identical in outward

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib Avenue

City

Isfahan

Province

Isfahan

Postal code

8135798111

Approval date

2015-12-22, 1394/10/01

Ethics committee reference number

IR.MUI.REC.1394.3.963

Health conditions studied

1

Description of health condition studied

migraine

ICD-10 code

G43.9

ICD-10 code description

Migraine, unspecified

Primary outcomes

1

Description

Migraine symptoms (severity, frequency and average duration of migraine attacks)

Timepoint

At first and end of intervention

Method of measurement

Questionnaire

2

Description

C-reactive protein (CRP)

Timepoint

At first and end of intervention

Method of measurement

Laboratory analysis (blood test)

Secondary outcomes

1

Description

Migraine Disability Assessment

Timepoint

At first and end of intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Supplementation of zinc sulfate (220 mg including 50 mg of elemental zinc, Alhavi Company), every day 1 supplement, 8 weeks

Category

Treatment - Drugs

2

Description

control group: placebo (made at the School of Pharmacy, Isfahan University of Medical Sciences), every day 1 supplement, 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Aliasghar hospital clinic

Full name of responsible person

Dr. Gholamreza Askari

Street address

Isfahan University of Medical Sciences, Hezar Jerib Avenue

City

Isfahan

Province

Isfahan

Postal code

8135798111

Phone

+98 31 3792 3171

Email

askari@mui.ac.ir

2

Recruitment center

Name of recruitment center

Imam Mousa Sadr Clinic

Full name of responsible person

Dr. Gholamreza Askari

Street address

Isfahan University of Medical Sciences, Hezar Jerib Avenue

City

Isfahan

Province

Isfahan

Postal code

8135798111

Phone

+98 31 3792 3171

Email

askari@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, University of Medical Sciences of Esfahan

Full name of responsible person

Dr Amir mansour alavi

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave

City

Isfahan

Province

Isfahan

Postal code

8135798111

Phone

+98 31 3792 3175

Email

am.alavi@nutr.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, University of Medical Sciences of Esfahan

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

Esfahan University of Medical Sciences

Full name of responsible person

Hedieh Ahmadi

Position

MSc of Nutrition

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave

City

Isfahan

Province

Isfahan

Postal code

8135798111

Phone

+98 31 3792 3171

Fax**Email**

hedieh_ahmadi85@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Gholamreza Askari

Position

PhD of Nutrition sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave

City

Isfahan

Province

Isfahan

Postal code

8135798111

Phone

+98 31337923171

Fax**Email**

askari@mui.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Hedieh Ahmadi

Position

MSc of Nutrition

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave

City

Isfahan

Province

Isfahan

Postal code

8135798111

Phone

+98 31 3792 3171

Fax**Email**

hedieh_ahmadi85@yahoo.com

Web page address**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