Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Investigating the effect of evening primrose oil on reducing the severity of headache and disability due to menstrual migraine

Protocol summary

Study aim
Investigating the effect of evening primrose oil on reducing the intensity of headache and disability in patients with menstrual migraine referred to the Neurology Clinic of Arak University of Medical Sciences.

Design
This study is a before and after clinical trial with parallel groups. It is three-blind. The sample size is 40 people. They are randomly divided into two control and intervention groups (block randomization method with the size of 4 blocks and the number of 6 blocks).

Settings and conduct
People referring to the neurology clinics of Arak city (Valiasr Clinic-Imam Reza Clinic) suffering from menstrual migraine are randomly divided into two groups of 20 people, control and intervention by the intern. The control group receives common treatments along with placebo, the intervention group in addition Common treatments receives 2 pearls of 1000 mg evening primrose oil daily from 5 days before to 5 days after menstruation for 3 months.

Participants/Inclusion and exclusion criteria
Criteria for entering the study: Age 18 to 55 years Not taking drugs other than prescribed drugs Obtaining informed consent from the patient Exclusion criteria: Menopause The occurrence of allergic reactions or drug side effects Hospitalization due to illness

Intervention groups
People who have the conditions to enter the study will be randomly divided into 2 groups of 20 people (control and intervention) by the project manager. The control group received common treatments (including sodium valproate 200 mg twice a day and nortriptyline 25 mg daily) along with placebo, the intervention group, in addition to the common treatments, received 2 Pearls 1000 mg evening primrose oil daily from 5 days before They receive it 5 days after menstruation for 3 months.

Main outcome variables
Severity of headache and disability caused by menstrual migraine

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230409057857N1**
Registration date: **2023-05-02, 1402/02/12**
Registration timing: **prospective**

Last update: **2023-05-02, 1402/02/12**
Update count: **0**

Registration date
2023-05-02, 1402/02/12

Registrant information

Name
Farzaneh Mohammadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3417 3036

Email address
nasimsharifi37@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-31, 1402/03/10

Expected recruitment end date
2024-03-10, 1402/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigating the effect of evening primrose oil on reducing the severity of headache and disability due to menstrual migraine

Public title
Investigating the effect of evening primrose oil on reducing the severity of headache and disability due to menstrual migraine

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 to 55 years old Certain menstrual migraine diagnosed based on IHS classification and the neurologist opinion Not using other drugs (psychoactive and opiate) Not suffering from another chronic illness except migraine Getting informed consent

Exclusion criteria:

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

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, randomization will be done using the block randomization method. A block size of 4 is considered. Therefore, we will have 6 blocks in the following order: AABB (1), ABAB (2), ABBA (3), BBAA (4), BABA (5), BAAB (6), each of which is numbered and addresses 4 patients. will be used; That is, if block number 2 is selected in the lottery, the first patient will receive treatment A (morangiola), the second patient will receive treatment B (placebo), the third patient will receive treatment A (morangiola) and the fourth patient will receive treatment B (placebo). The fifth patient will be randomly selected from one of the blocks and the type of treatment will be allocated to the fifth to eighth patients according to the block, and this process will be repeated until the end of sampling. The lottery is also done in such a way that the numbers of the blocks are written in folded papers and then another person (other than the researcher) takes one of the papers each time to determine the block number.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study, the doctor, the patient, and the statistical analyst are not aware of the allocation of patients in the intervention and control groups. In this way, the specialist doctor only examines the patients according to the criteria of the International Headache Society (IHS) to meet the conditions for entering the study, but is not involved in the randomization of their allocation; This is done by an intern colleague. In order to avoid the knowledge of the patients, the drug and placebo (which look the same) are removed from their original packaging and placed in paper packages of the same shape so that they cannot be distinguished. Also, in order to avoid the knowledge of the statistical analyst, the control and intervention groups are marked with code one and two, so that only the intern (researcher) is aware of the control and intervention groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Arak University of Medical Sciences

Street address
Masumeh dormitory, Medical science university of Arak, Sardasht Avenue, Arak town

City
Arak

Province
Markazi

Postal code
3848176941

Approval date
2023-03-19, 1401/12/28

Ethics committee reference number
IR.ARAKMU.REC.1401.338

Health conditions studied

1

Description of health condition studied
menstrual migraine

ICD-10 code
G43.82

ICD-10 code description
Menstrual migraine, not intractable

Primary outcomes

1

Description
Severity of headache and degree of disability caused by

menstrual migraine

Timepoint

Before the intervention, 3 months after the intervention

Method of measurement

Visual Analogue Scale, Migraine Disability Assessment

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: intervention group receives common treatments (including sodium valproate 200 mg twice a day and nortriptyline 25 mg daily) along with 2 pearls 1000 mg evening primrose oil manufactured by Barij Essential Oil Company of Iran from 5 days before to 5 days after for 3 months. The headache severity visual scale questionnaire and the migraine disability severity questionnaire are completed before the intervention and by a researcher in the form of questions from the patients and after 90 days of drug administration. After data collection, statistical analysis will be done using SPSS version 22 software and related statistical tests.

Category

Treatment - Drugs

2

Description

Control group: The control group receives common treatments (including sodium valproate 200 mg twice a day and nortriptyline 25 mg daily) along with 2 pearl placebo daily from 5 days before to 5 days after menstruation for 3 months.The headache severity visual scale questionnaire and the migraine disability severity questionnaire are completed before the intervention and by a researcher in the form of questions to the patients and after 90 days of drug administration. After data collection, statistical analysis will be done using SPSS version 22 software and related statistical tests.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr clinic, Imam Reza clinic

Full name of responsible person

Farzaneh Mohammadi

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Masumeh dormitory, Medical science university of Arak, Sardasht Avenue, Arak town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mehdi Salehi

Street address

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Farzaneh Mohammadi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Position
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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