

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Silybum Marianum on the treatment of patients with migraine headache referred to the clinics of Arak University of Medical Sciences

Protocol summary

Summary

As various studies have shown that seeds including Milk thistle herb is effective in treating certain neurological disorders. This study intends to evaluate the impact of Silybum marianum in improving migraine headaches. Migraine patients who have conditions in the study were divided into two groups: the first group and the second group received placebo medication livergol will be without the patient to know in which category. After 30 days to two months of treatment, patients are evaluated in terms of severity of migraine headache.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022026667N1**
Registration date: **2016-04-22, 1395/02/03**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-04-22, 1395/02/03

Registrant information

Name

Ali Jadidi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3508

Email address

jadidi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2017-07-01, 1396/04/10

Expected recruitment end date

2018-03-30, 1397/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Silybum Marianum on the treatment of patients with migraine headache referred to the clinics of Arak University of Medical Sciences

Public title

The effect of Silybum Marianum on treatment of migraine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having a history of migraines for 6 months; Headache frequency by at least three times a month; Age 15 to 50 years; Avoiding the use of prophylactic medication. Exclusion criteria: Unwillingness to continue the study

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Faculty of Nursing and Midwifery, Basij Square,
Taleghani Avenue, Arak

City

Arak

Postal code

Approval date

2016-01-18, 1394/10/28

Ethics committee reference number

IR.ARAKMU.REC.1394.282

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

headache

Timepoint

Before, 30 and 60 days after intervention

Method of measurement

Questionnaire of visual analog scale

Secondary outcomes

1

Description

Disability

Timepoint

Before, 30 and 60 days after intervention

Method of measurement

Questionnaire of MIDAS

Intervention groups

1

Description

The intervention group, in addition to drugs, Livergol tablets 70 mg, twice a day for two months will be given.

Category

Treatment - Drugs

2

Description

For the control group, in addition to the medications, administered twice daily placebo pills for two months, that looks like a tablet of Livergol.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Ali Jadidi

Street address

Vali Asr Square, Imam Khomeini St, Arak.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Rezai Ashtiani

Street address

Alamolhoda St, Arak University of Medical Sciences,
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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
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty