Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 dayes after intervention
Method of measurement
Questionnaire of visual analog scale

Secondary outcomes

1

Description
Disability
Timepoint
Before, 30 and 60 dayes 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
Arak

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, Arak
City
Arak
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

Arak University of Medical Sciences

Full name of responsible person

Ali Jadidi

Position

Msc of Nursing

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Nuorologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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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