

# 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

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**  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Email**  
jadidi@arakmu.ac.ir  
**Web page address**

## 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*