Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of treatment of constipation by lactoluse on the migraine improving in patients with migraine headache

Protocol summary

Summary

As various studies have shown that constipation severity of migraine headaches, this study intends to evaluate the effect of constipation treatment to improve migraine headaches. Therefore, patients with migraine who suffer from constipation are also divided into two groups: Lactulose syrup is given to the first group and the second group is given a placebo 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: **IRCT2016022226667N3**
Registration date: **2016-04-03, 1395/01/15**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-04-03, 1395/01/15

Registrant information

Name
Ali Jadidi
Name of organization / entity
Arak University of Medical Sciences
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Iran (Islamic Republic of)
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jadidi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2016-04-30, 1395/02/11

Expected recruitment end date

2016-08-31, 1395/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of treatment of constipation by lactoluse on the migraine improving in patients with migraine headache

Public title

The effect of treatment of constipation on improving 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)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

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, Arak University of Medical Sciences, Sardasht, Arak

City

Arak

Postal code

Approval date

2016-01-13, 1394/10/23

Ethics committee reference number

IR.ARAKMU.REC.1394.283

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, one and two moanth after intervention

Method of measurement

Questionnaire of visual analoge scale

Secondary outcomes

1

Description

Disability

Timepoint

Before, one and two mounth after intervention

Method of measurement

Questionnaire of MIDAS

Intervention groups

1

Description

In the intervention group, as long as patients treated constipation, in addition to the drug, given daily for 15 to 30 cc lactulose syrup.

Category

Treatment - Drugs

2

Description

The control group, in addition to medication, placebo given daily 20 cc; That is poured into the same bottles.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak University of Medica lSciences

Full name of responsible person

Street address

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Alireza Ashtiani

Street address

Medical School, Arak University of Medical Sciences, Sardasht, 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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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