Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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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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