Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effectiveness of Iraj Fiqra herbal pills in the treatment of migraine headaches: A randomized, double blind, placebo controlled trial

Protocol summary

Study aim
Evaluation of the effects of Iraj Fiqra herbal pills in the treatment of migraine

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients. For randomization, we will use the restricted randomization method of block randomization.

Settings and conduct
Setting: Physician Office. Intervention: Eligible patients are randomly assigned to two groups of standard migraine treatment with placebo or standard treatment with Iarj fiqra. Eligible patients receive routine migraine treatment with one Iraj Fiqra pill and the other group receive routine treatments with placebo tablets. The MIDAS (migraine disability assessment) questionnaire will be completed at the beginning of the study and two months later, the HIT-6 questionnaire (headache impact test -6) at the beginning of the first and second months of the study.

Participants/Inclusion and exclusion criteria
Patients with migraine without aura will be included in the study. Patients will be excluded from the study if they have chronic headache, pregnancy and lactation, the presence of some underlying disease and the concomitant use of certain medications, use of migraine prevention medication, drug or alcohol abuse and patient dissatisfaction.

Intervention groups
Eligible patients receive regular migraine treatment with a 500 mg Iraj Fiqra tablet for two months. The control group receives the usual treatments along with placebo pills

Main outcome variables
The primary outcome will include the evaluation of the number, severity, and duration of migraine attacks.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20081208001497N9**
Registration date: **2021-08-20, 1400/05/29**
Registration timing: **prospective**

Last update: **2021-08-20, 1400/05/29**
Update count: **0**

Registration date
2021-08-20, 1400/05/29

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-22, 1400/05/31

Expected recruitment end date
2022-05-21, 1401/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of Iraj Fiqra herbal pills in the treatment of migraine headaches: A randomized, double blind, placebo controlled trial

Public title
Evaluation of the effectiveness of Iraj Fiqra herbal pills in the treatment of migraine headaches

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having migraine without aura (according to the criteria of the International Headache Association (HIS), which is diagnosed by the physician Age between 18 and 65 History of migraine of at least one year The first migraine attack at the age of less than fifty years Have at least three attacks per month in the last three months Having a score higher than 6 according to the MIDAS questionnaire

Exclusion criteria:
Having headaches between two migraine attacks that are indistinguishable from migraine attacks Chronic tension headache or other types of headache for more than 15 days a month Pregnancy and lactation The presence of underlying heart problems such as arrhythmias History of biliary problems Comorbidities with inflammatory bowel diseases such as ulcerative colitis and Crohn's disease History of hemorrhoids Concomitant use of sedatives such as phenobarbital Concomitant use of diuretics, oral corticosteroids Concomitant use of laxatives such as polyethylene glycol or magnesium hydroxide Daily consumption of migraine prophylaxis for the past month Take at least three migraine medications for prophylaxis over the past ten years Drug or alcohol abuse Patient dissatisfaction

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples will be randomized by random blocking method with blocks of 4 which generated by Random Allocation software version 2. Blocking and allocation sequence for concealment will be done by the person not involved in the research (Allocation Concealment). The sample allocation ratio will be (1: 1 Allocation) and will be divided into two groups of drug recipients and placebo (Assignment). Drugs will then be given to patients based on the blocks obtained and in the order of allocation.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be performed as double-blind. The drug and placebo packing package and code allocation is done by the researcher involved in the research and then provided to the main researcher. In this way, the physician and patients will not know the contents of the packages and the type of codes and will not know which of the two control or test groups it belongs to.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, P.O. Box 319, Hezar-Jerib Ave.

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81746 73461

Approval date
2021-07-05, 1400/04/14

Ethics committee reference number
IR.MUI.RESEARCH.REC.1400.162

Health conditions studied

1

Description of health condition studied
Migraine

ICD-10 code
G43.0

ICD-10 code description
Migraine without aura

Primary outcomes

1

Description
Evaluation of the number of migraine attacks

Timepoint

Upon arrival, first and second month

Method of measurement

MIDAS questionnaire (migraine disability assessment) and HIT-6 questionnaire (headache impact test -6)

2

Description

Evaluation of the severity of migraine attacks

Timepoint

Upon arrival, first and second month

Method of measurement

MIDAS questionnaire (migraine disability assessment) and HIT-6 questionnaire (headache impact test -6)

3

Description

Evaluation of the duration of migraine attacks

Timepoint

Upon arrival, first and second month

Method of measurement

MIDAS questionnaire (migraine disability assessment) and HIT-6 questionnaire (headache impact test -6)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Eligible patients receive regular migraine treatment with a 500 mg tablet of Iaraj Fiqra (NIAK Pharmaceutical Company) for two months. Common medications include triptans, ergotamine derivatives, analgesics like NSAIDs, acetaminophen, and anti-emetic drugs such as metoclopramide and corticosteroids.

Category

Treatment - Drugs

2

Description

Control group: They receive the usual treatments along with placebo pills. This pill is prepared by NIAK Pharmaceutical Company and contains exponents such as lactose and magnesium stearate without active ingredient.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Physician office

Full name of responsible person

Dr Fariborz Khorvash

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

54710

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Published article
When the data will become available and for how long
One year
To whom data/document is available
All people
Under which criteria data/document could be used
No condition
From where data/document is obtainable
Scientific responded of the study
What processes are involved for a request to access data/document
Email to corresponding author
Comments