

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The effect of Migraine Cut herbal nasal spray on headache severity and quality of life in patients with migraine

Protocol summary

Study aim

The effect of Migraine Cut herbal nasal spray on headache severity and quality of life in patients with migraine

Design

Clinical trial with control group with parallel groups, phase 2-3 on 80 patients

Settings and conduct

This study is performed in Al-Zahra Hospital in Isfahan. At the beginning of the intervention, the severity of headache and quality of life were measured by a questionnaire. Patients are treated with a migraine cut spray or placebo, and the measurements are repeated after 3 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: newly diagnosed case of migraine, not using migraine medications, age 18 to 60 years, have a minimum literacy rate, satisfaction with participation in this study. Exclusion criteria: pregnancy and lactation, suffering from any chronic physical and mental illness, previous use of migraine prophylaxis, contraindications to anticonvulsant drugs, consumers of anticoagulants, epilepsy, chronic diseases of the gastrointestinal tract

Intervention groups

Intervention group: Patients in this group are routinely treated for migraine prophylaxis, including Depakine 250 mg 1 time per night, and also given a migraine cut nasal spray every 6 hours between 9 am and 9 pm, 2 puffs each time. It is also given in each nasal cavity. At the beginning of the interventions and after 3 months, the severity of headaches and their quality of life will be measured by a questionnaire. Control group: Patients in this group are routinely treated for migraine prophylaxis, including Depakine 250 mg 1 time per night, and they are also given a placebo nasal spray containing sodium chloride, according to the same instructions as the intervention group. At the beginning of the interventions and after 3 months, the severity of headaches and their quality of life will be measured by a questionnaire.

Main outcome variables

Headache severity and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210503051168N1**

Registration date: **2021-06-09, 1400/03/19**

Registration timing: **prospective**

Last update: **2021-06-09, 1400/03/19**

Update count: **0**

Registration date

2021-06-09, 1400/03/19

Registrant information

Name

Ali Fathi jozdani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3451 3020

Email address

afg26oct@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-10, 1400/04/19

Expected recruitment end date

2021-08-10, 1400/05/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Migraine Cut herbal nasal spray on headache severity and quality of life in patients with migraine

Public title

Migraine Cut herbal nasal spray and headache

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Newly diagnosed case of migraine Not using migraine medications Age 18 to 60 years Have a minimum literacy rate Satisfaction with participation in this study

Exclusion criteria:

Pregnancy and lactation Suffering from any chronic physical and mental illness Previous use of migraine prophylaxis Contraindications to anticonvulsant drugs Consumers of anticoagulants Epilepsy Chronic diseases of the gastrointestinal tract

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**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, Hezar Jarib Ave., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-05-28, 1400/03/07

Ethics committee reference number

IR.MUI.MED.REC.1400.161

Health conditions studied**1****Description of health condition studied**

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes**1****Description**

Severity of headache

Timepoint

At the beginning of the intervention and after three months

Method of measurement

Visual Analogue Scale questionnaire

2**Description**

Quality of Life

Timepoint

At the beginning of the intervention and after three months

Method of measurement

Migraine Disability Assessment scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients in this group are routinely treated for migraine prophylaxis, including Depakine 250 mg 1 time per night, and also given a migraine cut nasal spray every 6 hours between 9 am and 9 pm, 2 puffs each time. It is also given in each nasal cavity. At the beginning of the interventions and after 3 months, the severity of headaches and their quality of life will be measured by a questionnaire.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group are routinely treated for migraine prophylaxis, including Depakine 250 mg 1 time per night, and they are also given a placebo nasal spray containing sodium chloride, according to the same instructions as the intervention group. At the beginning of the interventions and after 3 months, the severity of headaches and their quality of life will be measured by a questionnaire.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Heliya Hemasian

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No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

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h.hemAsian@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

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haghjoo.sh@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Esfahan University of Medical Sciences

Full name of responsible person

Heliya Hemasian

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Neuroscience

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Person responsible for scientific inquiries

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Name of organization / entity

Esfahan University of Medical Sciences

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Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Isfahan University of Medical Sciences website

What processes are involved for a request to access data/document

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments