

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Investigation of the effectiveness of MigraineCut on the intensity, duration and frequency of migraine headaches of migraineurs referring to Aramesh Tehran pain clinic

Protocol summary

Study aim

Study the therapeutic effects of MigraineCut herbal drug on migraine headaches

Design

Data were collected and compared on the basis of indicators, guidelines and forms of the International Headache Society (IHS). The medical records of patients with confirmed migraine were compiled. Patients received the necessary training about the course of treatment, timing, medication intake, migraine markers, how to fill out daily forms.

Settings and conduct

Following the diagnosis of migraine in the study group by an expert at the Aramesh Clinic, an explanation of the treatment process and completion of the diary form and the services she/he will receive during this period will be provided. Each month, after the necessary documentation is completed by the patient and after receiving the diary and expert consultation, the necessary medication is delivered to the patient to complete the course of treatment. After completing the course of treatment, additional explanations were given to keep track of the treatment process and how patients were informed about the results of the study.

Participants/Inclusion and exclusion criteria

Patients with symptoms of migraine headaches were added to the study after a specialist visit and approval. If their migraine counselor reports that they have probable migraine, migraine associated with overused headaches and complex headaches, they will be excluded. Patients who drop out of treatment and do not provide adequate information to counselors are excluded from the study.

Intervention groups

The test group is a group that is undergoing treatment with MigraineCut (nasal spray). The control group is a group of patients with Migraine headaches without treatment with MigraineCut.

Main outcome variables

1- Change in the frequency 2- Change in the duration and 3- Change in the severity of the headaches. 4. Change in the clinical symptoms associated with the headaches.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170705034915N3**

Registration date: **2019-08-23, 1398/06/01**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-23, 1398/06/01**

Update count: **0**

Registration date

2019-08-23, 1398/06/01

Registrant information

Name

Farid Semsarha

Name of organization / entity

University of Tehran

Country

Iran (Islamic Republic of)

Phone

+98 21 8850 0280

Email address

fsemsarha@mimdaroo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-19, 1398/01/30

Expected recruitment end date

2021-06-02, 1400/03/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effectiveness of MigraineCut on the intensity, duration and frequency of migraine headaches of migraineurs referring to Aramesh Tehran pain clinic

Public title

Study of the effect of MigraineCut drug on migraine headaches

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with migraine after being diagnosed by a neurologist. Male or female patient has a migraine attack at least one month per year. Patient aged between 16 and 60 years who has the opportunity to complete the diary form and communicate effectively with the counselor. Patient that doesn't have susceptibility to herbal medicines.

Exclusion criteria:

Patient with probable migraine headaches Patients with medication overused headaches Patients with complex headaches Patients who provide incomplete data and information to the counselor. Patients who do not wish to start or continue treatment with knowledge of the conditions of the study

Age

From **16 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **492**

Randomization (investigator's opinion)

N/A

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 azad University-Research and science branch

Street address

Floor 13, Unit A, Central Headquarters of the Ministry of Health Education, Between South Falamak and Zarafshan, Simay Iran Avenue, Ghods Town, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2019-04-17, 1398/01/28

Ethics committee reference number

IR.IAU.SRB.REC.1398.008

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

Headaches frequency

Timepoint

Counting the number of headaches from the beginning of the study (before the intervention), 30, 60, 90, and 120 days after the start of the MigraineCut.

Method of measurement

headache diary form

2

Description

Headache intensity

Timepoint

Record the intensity of each migraine attack every month for up to 4 months during the study.

Method of measurement

Headache diary form

3

Description

Headache duration

Timepoint

Calculate the duration of headaches before the intervention, and during 30, 60, 90, and 120 days from the onset of intervention with cutaneous migraine.

Method of measurement

Headache diary form

Secondary outcomes

1

Description

Changes in the clinical symptoms of migraineurs

Timepoint

Clinical symptoms of patients, such as sensitivity to light and sound before intervention, and 30, 60, 90, and 120 days after intervention are investigated.

Method of measurement

Headache diary form and expert visit

Intervention groups

1

Description

Migraine patients: Use of MigraineCut nasal spray containing extract of herbs intended to reduce headaches indices and clinical signs of migraine within 120 days at an authorized dose of a puff in every nasal cavity every 3 hours.

Category

Treatment - Drugs

2

Description

Control group: Migraineurs group with no treatment

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Aramesh tehran pain clinic

Full name of responsible person

Nima Mosenzadeh (Neurologist)-Dr.Farid SemsarhaDr.

Street address

No. 4, 4th Street, Ganbarzadeh Street, Shahid Beheshti Street

City

Tehran

Province

Tehran

Postal code

1533853613

Phone

+98 21 9662 1414

Email

fsemsarha@mimdaroo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

MIMDaroo Pharmaceutical Co.

Full name of responsible person

Farid Semsarha

Street address

No. 4, 4th Street, Ganbarzadeh Street, Shahid Beheshti Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1533853613

Phone

+98 21 9662 1410

Email

Info@MIMDaroo.com

Web page address

<https://www.mimdaroo.com/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

MIMDaroo Pharmaceutical Co.

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

MIMDaroo Pharmaceutical Co.

Full name of responsible person

Farid Semsarha

Position

Assistante professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

No. 4, 4th Street, Ganbarzadeh Street, Shahid Beheshti Street, Tehran, Iran

City

Tehran

Province

Tehran
Postal code
1533754716
Phone
+98 21 9662 1410
Email
fsemsarha@mimdaroo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

MIM Daroo

Full name of responsible person

Farid Semsarha

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

No. 4, 4th Street, Ganbarzadeh Street, Shahid Beheshti Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1533754716

Phone

+98 21 9662 1410

Email

fsemsarha@mimdaroo.com

Person responsible for updating data

Contact

Name of organization / entity

MIM daroo Pharmaceutical Co.

Full name of responsible person

Farid Semsarha

Position

Assistant Professor of Biophysics

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

No. 4, 4th alley, Eshghyar street, Ghanbarzadeh st., Beheshti Ave., Terhan, Iran

City

Tehran

Province

Tehran

Postal code

1533853613

Phone

+98 21 9662 1410

Fax

+98 21 8875 2115

Email

fsemsarha@mimdaroo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available