# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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 symptums 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
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Iran (Islamic Republic of)
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**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**

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**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**

Headeches 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 diray 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 diray 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: Migrainures 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
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
MIMDaroo Pharmaceutical Co.
**Full name of responsible person**
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No. 4, 4th Street, Ganbarzadeh Street, Shahid Beheshti Street, Tehran, Iran
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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**
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Traditional Medicine
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## Person responsible for updating data

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## 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