

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Design, fabrication and evaluation of physical and chemical properties and evaluation of the clinical effect of formulation of targeted cerebral drug delivery system through the nose containing Sumatriptan in acute migraine attacks

Protocol summary

Study aim

Rapid treatment of acute migraine attacks

Design

A clinical trial with two groups of crossover, non-randomized, phase 3 on 73 patients

Settings and conduct

Imam Reza Hospital in Kermanshah - the people who enter the study are among those who go to the hospital with a headache complaint and after screening these people are invited to cooperate if they have the conditions to enter the study. Patients are divided into two groups. 37 people in two The first migraine attack uses Sumatriptan 10 mg nasal spray and the next two attacks use 50 mg Sumatriptan oral tablet. Washing period: Concomitant use of sumatriptan with a monoamine oxidase is contraindicated. There should be a 24-hour interval between taking sumatriptan with other headache medications such as ergotamine, dihydroergotamine, and methyl ergonovine to prolong the effects of long-term contraction. Concomitant use of (SSRI) use of with sumatriptan is not recommended. Concomitant use of cabergoline and bromocriptine is also contraindicated

Participants/Inclusion and exclusion criteria

inclusion: Individuals with 2 to 8 migraine attacks per month and a history of more than one year of migraine
exclusion: History of congenital heart disease, Cardiovascular and Pulmonary disease, treated cardiac arrhythmias, Angina, Cerebrovascular disease- Pregnant patients, History of hypertension, History of stroke Brain, Sumatriptan allergy, History of coronary artery disease

Intervention groups

Intervention group 1: Use of 10 mg nasal spray in the first two Migraine attacks and use of 50 mg oral tablet in the second two Migraine attacks
Intervention group two:

using oral tablet in the first two Migraine attacks and using Sumatriptan nasal spray in the second two Migraine attacks

Main outcome variables

Severity of the headache Side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180120038450N4**

Registration date: **2022-04-03, 1401/01/14**

Registration timing: **retrospective**

Last update: **2022-04-03, 1401/01/14**

Update count: **0**

Registration date

2022-04-03, 1401/01/14

Registrant information

Name

Shahla Mirzaeei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3824 0526

Email address

shahlamirzaeei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design, fabrication and evaluation of physical and chemical properties and evaluation of the clinical effect of formulation of targeted cerebral drug delivery system through the nose containing Sumatriptan in acute migraine attacks

Public title

Design, fabrication and evaluation of physical and chemical properties and evaluation of the clinical effect of formulation of targeted cerebral drug delivery system through the nose containing Sumatriptan in acute migraine attacks

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with 2 to 8 migraine attacks per month History of more than one year with migraine(with aura or without aura)

Exclusion criteria:

Pregnancy History of high blood pressure History of myocardial infarction History of stroke Allergy to sumatriptan History of coronary artery disease History of congenital heart disease Cardiovascular disease Pulmonary disease Cardiac arrhythmias Angina Cerebrovascular disease

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **73**

More than 1 sample in each individual

Number of samples in each individual: **4**

Sumatriptan oral tablets and nasal spray

Randomization (investigator's opinion)

Not randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

Street address

Central Organization of Kermanshah University of Medical Sciences-Shahid Beheshti Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6714858743

Approval date

2022-01-03, 1400/10/13

Ethics committee reference number

IR.KUMS.REC.1400.661

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

Acute migraine attack

ICD-10 code

G43

ICD-10 code description

Migraine

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

Migraine headache condition

Timepoint

Before the intervention and a month later

Method of measurement

Visual Analogue Scale/Headache Impact Test

Secondary outcomes**1****Description**

adverse effect

Timepoint

At the onset of a migraine attack up to two hours after taking the drug

Method of measurement

Side effects questionnaire

Intervention groups

1

Description

Group 1: 37 people are non randomized selected and use Sumatriptan nasal spray(10mg) in the first two migraine attacks and Sumatriptan oral tablet (50mg)in the next two attacks.

Category

Treatment - Drugs

2

Description

The second group: 36 people are randomly selected and in the first two migraine attacks they use Sumatriptan oral tablet(50mg) and in the next two attacks they use Sumatriptan nasal spray(10mg).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam reza educational hospital, Kermanshah

Full name of responsible person

Payam sariaslani

Street address

Faculty of Pharmacy-Parstar Blvd-Daneshgah St-Shahid Shiroodi Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6714415153

Phone

+98 83 3426 6780

Email

Shahlamirzaeei@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Shahla mirzaei

Street address

Faculty of Pharmacy-Parstar Blvd-Daneshgah St-Shahid Shiroodi Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6714415153

Phone

+98 83 3427 6489

Email

shahlamirzaeei@gmail.com

Grant name

120230000rial

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Azar mollaei

Position

Pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

Bustan Girls' Dormitory 2-Nurse Boulevard, in front of Imam Reza Hospital

City

kermanshah

Province

Kermanshah

Postal code

6714438621

Phone

+98 87 3352 2321

Email

azar_mollaei_98@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

shahla mirzaei

Position

Assistant Professor of Pharmaceutics

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy-Parstar Blvd-Daneshgah St-
Shahid Shiroodi Blvd

City

kermanshah

Province

Kermanshah

Postal code

6714415153

Phone

+98 83 3426 6780

Email

shahlamirzaeei@gmail.com

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

Kermanshah University of Medical Sciences

Full name of responsible person

Azar mollaei

Position

Pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

Bostan Sisters Dormitory 2-Nurse Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6714438621

Phone

+98 87 3352 2321

Email

azar_mollaei_98@yahoo.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

Undecided - It is not yet known if there will be 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