

# 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