Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of PSM® ointment along with common therapies in patients with refractory headache to treatment

Protocol summary

Study aim
Determining the effect of PSM® ointment along with common therapies in patients with refractory headache
Design
Clinical trial with control group, double-blind, randomized, phase 3 on 60 patients. Patients will be assigned as a random permutation block in two groups.
Settings and conduct
We will evaluate patients referred to a neurology clinic of Razi Hospital in Birjand with refractory headache more than 15 days a month for three consecutive months of headache.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Refractory headache more than 15 days a month for three consecutive months Exclusion criteria: Warning signs associated with increased intracranial pressure, Abnormal brain imaging, Focal brain lesions, Infectious CNS disease, Psychiatric diseases, Symptoms of tumors and cerebral occupying lesions, Drug abuse, Pregnant and lactating women, Elective discontinuation of the study, Skin reaction to the ointment, Exacerbation of symptoms or any new neurological complications.
Intervention groups
Intervention group: Ointment containing nortriptyline, prednisolone, aspirin and biperiden in a base of eucerin along with common therapy Control group: Eucerin ointment along with common therapy
Main outcome variables
Headache severity based on Visual Analogue Scale, Duration of headache, Frequency of headache

General information

Reason for update
Acronym
®PSM
IRCT registration information
IRCT registration number: **IRCT20201228049868N1**
Registration date: **2021-01-19, 1399/10/30**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-19, 1399/10/30**
Update count: **0**
Registration date
2021-01-19, 1399/10/30

Registrant information
Name
Seyyed Mohammad Mousavi Mirzaei
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 56 3162 6020
Email address
mousavim903@bums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-01-03, 1399/10/14
Expected recruitment end date
2021-07-05, 1400/04/14
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of PSM® ointment along with common therapies in patients with refractory headache to treatment

Public title
Evaluation of the effect of PSM® ointment in refractory

headache to treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Refractory headache more than 15 days a month for three consecutive months

Exclusion criteria:

Warning signs associated with increased intracranial pressure Abnormal brain imaging Focal brain lesions Infectious CNS disease Psychiatric diseases Symptoms of tumors and cerebral occupying lesions Drug abuse Pregnant and lactating women Elective discontinuation of the study Skin reaction to the ointment Exacerbation of symptoms or any new neurological complications

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned as a random permutation block in two groups. Randomization was using random number generation. Thirty random numbers from 1 to 60 and these people are our intervention group.

Blinding (investigator's opinion)

Double blinded

Blinding description

All of the steps will be covered by the patient, physician and evaluators.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences , Ghaffari Street

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2020-10-12, 1399/07/21

Ethics committee reference number

IR.BUMS.REC.1399.334

Health conditions studied

1

Description of health condition studied

Refractory headache

ICD-10 code

8A80.2

ICD-10 code description

Chronic migraine

Primary outcomes

1

Description

Headache severity based on Visual Analogue Scale

Timepoint

Baseline and after one month

Method of measurement

Questionnaire

2

Description

Duration of headache

Timepoint

Baseline and after one month

Method of measurement

Questionnaire

3

Description

Frequency of headache

Timepoint

Baseline and after one month

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Adverse effects

Timepoint

Baseline and after one month

Method of measurement

Questionnaire

Intervention groups

1

Description
Intervention group: Ointment containing nortriptyline, prednisolone, aspirin and biperiden in a base of eucerin along with common therapy
Category
Treatment - Drugs

2

Description
Control group: Eucerin ointment along with common therapy
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurology Clinic of Razi Hospital
Full name of responsible person
Seyyed Mohammad Mousavi Mirzaei
Street address
Razi Hospital, Ghaffari Street
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Birjand
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9717844471
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mousavim903@bums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Toba Kazemi
Street address
Birjand University of Medical Sciences, Ghaffari Street
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9717853577
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research@bums.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand University of Medical Sciences
Proportion provided by this source
10
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
Birjand University of Medical Sciences
Full name of responsible person
Seyyed Mohammad Mousavi Mirzaei
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
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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
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