Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of MigraTeb's traditional medicine on the pain of migraine and tention headaches, A randomized clinical trial

Protocol summary

Study aim
The effect of MigraTeb's traditional medicine on the pain of migraine and tension headaches; A randomized clinical trial

Design
Two arm parallel group randomized trial with blinded postoperative care and outcome assessment

Settings and conduct
During 18 months, 124 patients diagnosed with migraine or tension headcases according to inclusion and exclusion criteria will be selected out of whom that are referred to Imam Reza and Farabi hospitals of Kermanshah University of Medical Sciences, then will be allocated in two same groups according to the final number of their files, the case and control groups will receive MigraTeb and placebo respectively. the patients will be evaluated for the intensity and frequency of headache 1 hour, weekly up to fourth week and analgesic consumption up to third month following intervention.

Participants/Inclusion and exclusion criteria
The inclusion criteria: the experience of headache attack twice a month. and the exclusion criteria: less than one year of headache initiation, pregnancy, malignancy, cluster headache (IHS 3), secondary headache (IHS 5-11) and cranial neuralgia (IHS 12)

Intervention groups
Intervention: MigraTeb Case group: The patients with Migraine or tension headache who are treated by MigraTeb Control Group: The patients with Migraine or tension headache who are treated by MigraTeb

Main outcome variables
Intensity and frequency of headache; the amount of drug consumption

General information

Reason for update

Acronym
میگرا طب و سردرد میگرن و تنشی

IRCT registration information
IRCT registration number: **IRCT20081007001310N13**
Registration date: **2020-03-13, 1398/12/23**
Registration timing: **prospective**

Last update: **2020-03-13, 1398/12/23**
Update count: **0**

Registration date
2020-03-13, 1398/12/23

Registrant information

Name
Alireza Ahmadi

Name of organization / entity
Kermanshah University of Medical Sciences

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Iran (Islamic Republic of)

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+98 83 3428 2670

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-20, 1399/02/01

Expected recruitment end date
2021-04-20, 1400/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of MigraTeb's traditional medicine on the pain of migraine and tention headaches, A randomized clinical

trial

Public title
Effect of MigraTeb's on the pain of migraine and tention headaches
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Experience of headache aatack twice a month
Exclusion criteria:
History of headache less than one year Pregnancy Malignancy Cluster Headache (IHS code 3) Secondary headaches (IHS 11-5) Cranial Neuralgia
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **124**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be divided into 2 groups according to the final number of the patient file, as if, the odds will be allocated to international group and evens in control group
Blinding (investigator's opinion)
Double blinded
Blinding description
Following primary visit by physician and according to inclusion and exclusion criteria, the patient will be transferred to care room, the dresses will be changed then a same mask will be applied on the head for both groups of the patients as if non of patient and care giver are aware of their therapeutic group. After one hour the mask will be washed and the head will be dried and the patient will be evaluated by the physician once again.
Placebo
Used
Assignment
Parallel
Other design features
For the first time in iran , the clinical effects of the drug is evaluated

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Kermanshah University of Medical Sciences central Building, Beheshti Blvd, Kermanshah, Iran
City
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Kermanshah
Postal code
6715847141
Approval date
2019-09-22, 1398/06/31
Ethics committee reference number
KUMS.REC.1398.684

Health conditions studied

1

Description of health condition studied
Migraine Headache
ICD-10 code
G43
ICD-10 code description
Migraine

2

Description of health condition studied
Tension Headache
ICD-10 code
G44.2
ICD-10 code description
Tension-type headache

Primary outcomes

1

Description
Intensity of Headache
Timepoint
one hour, weekly up to fourth week following in intervention
Method of measurement
Patient statement

2

Description
Frequency of headache
Timepoint
weekly up to fourth week following in intervention
Method of measurement
Patient statement

3

Description
Drug consumption
Timepoint

Before and 3 months following intervention

Method of measurement

American Pain Physicians Association table

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patients with Migraine or tension headache will be treated by MigraTeb as a lotion which is applied on forehead and face and following one hour is washed. This lotion is a combination of Allium rotundum and Urtica dioica extract. This compound is prepared by a traditional medicine pharmacist colleague at the Kermanshah School of Pharmacy. Frequency of use is one time. After an hour, the forehead is removed.

Category

Treatment - Drugs

2

Description

Control group: The patients with Migraine or tension headache will be treated by placebo as a lotion which is applied on forehead and face and following one hour is washed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital of Kermanshah University of Medical Sciences

Full name of responsible person

Alireza Ahmadi

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2

Recruitment center

Name of recruitment center

Farabi Hospital, Kermanshah University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

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Grant name

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
Alireza Ahmadi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
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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