Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating migraine from the perspective of Persian traditional medicine and the effectiveness of Persian herbal formulation on migraine associated with functional dyspepsia

Protocol summary

Study aim
Comparison of the effect of Persian traditional medicine product with Sodium Valproate on migraine headache with functional dyspepsia

Design
randomized double-blind clinical trial (phase 2) including 3 groups of 25 participants

Settings and conduct
75 patients were randomly divided into three groups of 25 participants and each group received double blind treatment by supervision of specialist according to the protocol

Participants/Inclusion and exclusion criteria
People with migraine headaches according to the International Classification of Headache Disorders 3rd edition (ICHD-III) with the approval of a neurologist 2) Patients with Functional Dyspepsia Based on Parkman Criteria and Parkman Functional dyspepsia Criteria 3) Patients aged 18 to 55 years Exclusion criteria 1) Patients with chronic and acute headaches with a diagnosis other than migraine 2) Patients with uncontrolled hypertension (160 systolic and 100 diastolic systolic blood pressure). 3) Patients with cancer 4) Pregnancy and lactation 5) Peptic Ulcer 6) The occurrence or diagnosis of any systemic physical or psychologic disease including liver, kidney, heart disease and any neurologic component of the migraine during the study 7) Use drugs that cause headaches themselves, such as nitroxanthine

Intervention groups
Group 1: herbal product capsule 750 mg + 200 mg depopacin tablet + 10 mg amitriptyline tablet Group 2: Depaxine 200 mg tablet + placebo capsule 750 mg herbal Group 3: 750 mg herbal product capsule + 200 mg placebo tablet

Main outcome variables
HIT-6 questionnaire score Parkman criteria score severity of headaches duration of headache Frequency of headache

General information

Reason for update

Acronym
no

IRCT registration information
IRCT registration number: **IRCT20170317033107N3**
Registration date: **2020-01-11, 1398/10/21**
Registration timing: **retrospective**

Last update: **2020-01-11, 1398/10/21**
Update count: **0**

Registration date
2020-01-11, 1398/10/21

Registrant information

Name
ali gholampour

Name of organization / entity
Mashhad medical science- iranian traditional college

Country
Iran (Islamic Republic of)

Phone
+98 51 3884 8930

Email address
gholampoura1@mums.ac.ir

Recruitment status
Recruitment complete

Funding source
University research departments

Expected recruitment start date
2017-05-22, 1396/03/01

Expected recruitment end date
2017-08-23, 1396/06/01

Actual recruitment start date
2017-07-06, 1396/04/15
Actual recruitment end date
2018-07-23, 1397/05/01
Trial completion date
2019-05-22, 1398/03/01

Scientific title
Investigating migraine from the perspective of Persian traditional medicine and the effectiveness of Persian herbal formulation on migraine associated with functional dyspepsia

Public title
Effectiveness of Persian herbal formulation on migraine associated with functional dyspepsia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Migraine headache concurrently with functional dyspepsia Migraine headache criteria based on the latest version and presentation of dyspepsia
Exclusion criteria:
Headache with non diagnosis of migraine Stomach disorder with non diagnosis of functional dyspepsia
Age
From **17 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**
Actual sample size reached: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple individualized randomization with statistical software
Blinding (investigator's opinion)
Double blinded
Blinding description
This study was a double-blind clinical trial in which patients and researchers were not informed of the treatment group and when entered into the Persian traditional pharmacy of Imam Reza Hospital and apothecary after viewing the number and referring to the numbers table and determining treatment group the medication was given 3 months each 15 days separately.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Central Organization of Mashhad University of Medical Sciences, Daneshgah St.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Approval date
2017-02-25, 1395/12/07
Ethics committee reference number
ir.mums.ac.rec.1395.585

Health conditions studied

1

Description of health condition studied
migraine associated with functional dyspepsia
ICD-10 code
G43, G43.1
ICD-10 code description
Migraine without aura [common migraine], Migraine with aura [classical migraine] Migraine: aura without headache basilar equivalents familial hemiplegic with: acute-onset aura prolonge

Primary outcomes

1

Description
Headache frequency
Timepoint
Baseline and after 4, 8 and12 weeks of intervention
Method of measurement
Number of episodes in month

2

Description
Headache duration
Timepoint
Baseline and after 4, 8 and12 weeks of intervention
Method of measurement
Duration of each episode (in hour)

3

Description
Headache severity
Timepoint
Baseline and after 4, 8 and12 weeks of intervention
Method of measurement
Visual Analog Scale

4

Description
Severity of functional dyspepsia
Timepoint
Baseline and 12 weeks after the intervention
Method of measurement
Parkman's criteria

Secondary outcomes

1

Description
Effect of headache on quality of life
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
HIT-6 questionaire

Intervention groups

1

Description
Intervention group 1": Three capsules of 750 mg of Persian Traditional Medicine Product (Contains Ginger, Amelah, Rose, Coriander) three times a day plus Depakin (Sanofi pharmaceutical company) two tablets of 200 mg each day and amitriptyline (Iran daroo pharmaceutical company) 1 tablet 10 mg once a day all of them for three months.
Category
Treatment - Drugs

2

Description
"Intervention group 2": Three capsules of 750 mg of Persian Traditional Medicine Product (Contains Ginger, Amelah, Rose, Coriander) three times a day plus Depakin placebo tablet twice a day.
Category
Treatment - Drugs

3

Description
"Control group": Three placebo capsules of 750 mg as like as Traditional Medicine Product capsules three times a day plus Depakin tablets 200 mg twice a day and amitriptyline tablet 10 mg once a day.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem educational hospital
Full name of responsible person
Dr.Karim Nikkhah
Street address
Ghaem educational hospital, Ahmadabad St.
City
Mashhad
Province
Razavi Khorasan
Postal code
9919991766
Phone
+98 51 3840 0000
Email
Quaem.Medical.Center@mums.ac.ir
Web page address
http://quaem.mums.ac.ir/index.php

2

Recruitment center
Name of recruitment center
Persian traditional medicine clinic
Full name of responsible person
Dr. Majid Anushirvani
Street address
Emam Reza educational hospital, Emam Reza Sq.
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3802 2500
Email
emamreza@mums.ac.ir

3

Recruitment center
Name of recruitment center
Emam Reza educational hospital, Gastroentrology clinic
Full name of responsible person
Dr.Mousalreza Hoseini
Street address
Emam Reza educational hospital, Emam Reza Sq.
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3854 3031
Email

emamreza@mums.ac.ir

Web page address

https://emamreza.mums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Saeed Eslami

Street address

Central organization of Mashhad university of medical sciences, Daneshgah St.

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 2081

Email

vcresearch@mums.ac.ir

Web page address

https://v-research.mums.ac.ir/

Grant name

-

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Ali Gholampour

Position

PhD student of Iranian tradditional medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

Emam Reza hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3884 8930

Fax

Email

Gholampoura1@mums.ac.ir

Web page address

http://tim.mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Anushirvani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

East door of Ferdowsi University, School of Persian and complementary medicine

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3884 8930

Fax

Email

dr.Anushiravani@gmail.com

Web page address

http://tim.mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ali Gholampour

Position

Phd student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

East door of Ferdowsi University, School of Persian

and complementary medicine

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Phone
0098518848930

Fax

Email
Gholampoura1@mums.ac.ir

Web page address
http://tim.mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The spss file contains the following information from the participants: demographic information HIT-6 questionnaire and parkman criteria scores

When the data will become available and for how long
6 month after publication of results

To whom data/document is available
The data is only accessible to researchers working in academic centers

Under which criteria data/document could be used
New research on the data of this study is allowed with the written permission of the corresponding author

From where data/document is obtainable
Contact corresponding author of the published article, Dr. Majid Anushiravani via following email address: dr.anushiravani@gmail.com

What processes are involved for a request to access data/document
1. send a request to corrsponding author via an academic email address 2. Check the request by corresponding author 3. If applicable, send the data file by email

Comments