Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Efficacy of “Etrifel” and “Mastaki” on monthly bouts of headache in Migraineurs with Gastric Headache.

Protocol summary

Summary

- This trial is designed to treat migraineurs with gastric dysfunction - It is a multicenter, phase I-II, single arm (before-after), non-randomized, open label study. - To be included in this study the patients should have the diagnosis of Migraine and also "Gastric Headache" according to the Iranian Traditional Medicine. should experience at least 3 attacks in a month. - They are excluded if have taken preventive drugs in the last 3 months, have history of drug abuse, have systemic or neurologic disease. - The study would have 30 participants - The participants firstly enter the run-in period for 4 weeks in which they receive no treatments and only record their symptoms in a "Headache Diary". Afterwards the intervention phase starts for 12 weeks and patients receive "Etrifel confection" before breakfast and "Mastic gum powder" before sleep. At the end the data is compared with the pre-treatment data. - The primary outcome is the headache frequency in a period of 4 weeks. The secondary outcomes are Pain severity and duration of attacks.

General information

Acronym

GHS- Gastric Headache Study

IRCT registration information

IRCT registration number: **IRCT2015092324150N1**
Registration date: **2017-01-08, 1395/10/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-01-08, 1395/10/19

Registrant information

Name

Majid Talafi Noghani

Name of organization / entity

Shahed university

Country

Iran (Islamic Republic of)

Phone

+98 21 5121 4055

Email address

m.noghani@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology of Shahed University
Barij Essence Pharmaceutical Company(R&D division)

Expected recruitment start date

2017-01-04, 1395/10/15

Expected recruitment end date

2017-06-05, 1396/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of “Etrifel” and “Mastaki” on monthly bouts of headache in Migraineurs with Gastric Headache.

Public title

Effect of Iranian Traditional Medicine drugs in the treatment of Migraine.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Male or female 18-65 years old; diagnosed since 6 months ago with Episodic or Probable Migraine ± aura by a specialist according to criteria from ICHD-III; having 3 to 14 attacks of migraine in a month from 3 months ago; diagnosed with Gastric Headache

according to Iranian Traditional Medicine Questionnaire; normal neurologic examination Exclusion criteria: Taking preventive drugs in the last 3 months; history of drug abuse; history of allergy to the trial drugs; pregnant or breast feeding women; systemic and other neurologic diseases

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Commitee of Shahed University

Street address
The Shahed faculty of Medicine, Abdollahzadeh str., Keshavarz Blv.

City
Tehran

Postal code

Approval date
2016-11-27, 1395/09/07

Ethics committee reference number
IR.Shahed.REC.1395.133

Health conditions studied

1

Description of health condition studied
Migraine

ICD-10 code
G43

ICD-10 code description
Migraine

Primary outcomes

1

Description
Headache frequency in a period of 4 weeks

Timepoint
before intervention, 4, 8, and 12 weeks after the start of intervention

Method of measurement
Questionnaire

Secondary outcomes

1

Description
Headache severity

Timepoint
before intervention, 4, 8, and 12 weeks after the start of intervention

Method of measurement
Visual Analgue Scale

2

Description
Headache duration

Timepoint
before intervention, 4, 8, and 12 weeks after the start of intervention

Method of measurement
Questionnaire

3

Description
The amount of rescue medication use in each attack

Timepoint
before intervention, 4, 8, and 12 weeks after the start of intervention

Method of measurement
Questionnaire

Intervention groups

1

Description
Etrifel confection, 10 grams(or maximum tolerated dose), once daily for 12 weeks, orally, before breakfast. Mastic gum powder, 3 grams(or maximum tolerated dose), once daily for 12 weeks, orally, before sleep.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mostafa Khomeini Hospital Clinics

Full name of responsible person

Majid Talafi Noghani(MD, PhD student in Iranian Traditional Medicine)

Street address

Mostafa Khomeini Hospital, Italia str., Felestin str.

City

Tehran

2

Recruitment center

Name of recruitment center

Iranian Traditional Medicine Clinic

Full name of responsible person

Majid Talafi Noghani(MD, PhD student in Iranian Traditional Medicine)

Street address

Dashtestan sevvom alley, Shariati str.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Technology of Shahed university

Full name of responsible person

Dr. Zahra Kiasalari

Street address

Shahed university, Khalij Fars Express way

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research and Technology of Shahed university

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Barij Essence Pharmaceutical Company (R&D division)

Full name of responsible person

Dr. Ahmadian (pharmacist)

Street address

2nd Floor, No. 132, Between Isar and Ariafar streets, Marzdaran Blv.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Barij Essence Pharmaceutical Company (R&D division)

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iranian Traditional Medicine Department, Shahed university

Full name of responsible person

Majid Talafi Noghani

Position

MD, PhD student in Iranian Traditional Medicine

Other areas of specialty/work

Street address

The Shahed Faculty of medicine, Abdollahzadeh str., Keshavarz blv.

City

Tehran

Postal code

Phone

+98 21 5121 4055

Fax

Email

M.Noghani@Shahed.ac.ir

Web page address

https://telegram.me/GHStudy

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iranian Traditional Medicine Department, Shahed university

Full name of responsible person

Majid Talafi Noghani

Position

MD, PhD student in Iranian Traditional Medicine

Other areas of specialty/work

Street address

The Shahed Faculty of medicine, Abdollahzadeh str.,

Keshavarz blv.
City
Tehran
Postal code
Phone
+98 21 5121 4055
Fax
Email
M.Noghani@Shahed.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Iranian Traditional Medicine Department, Shahed university
Full name of responsible person
Majid Talafi Noghani
Position
MD, PhD student in Iranian Traditional Medicine
Other areas of specialty/work
Street address
The Shahed Faculty of medicine, Abdollahzadeh str., Keshavarz blv.
City
Tehran
Postal code
Phone
00
Fax
Email
M.Noghani@Shahed.ac.ir
Web page address
https://telegram.me/GHStudy

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty