# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 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**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*