Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

The effect of Etrifel (a product of Iranian traditional medicine) on patients with migraine and gastrointestinal symptoms

Protocol summary

Study aim
The effect of Etrifel (a product of Iranian traditional medicine) on patients with migraine and gastrointestinal symptoms

Design
A randomized clinical trial with a control group based on community with parallel and double-blind groups.

Settings and conduct
A total of 124 patients with gastroenterological migraine referred to Shahid Sadoughi Clinic of Yazd were selected and randomly divided into two equal groups according to entry and exit criteria. Both groups received daily 200mg of sodium valproate and 50mg of placebo in the control group and 50mg of infusion in the intervention group. Patients evaluated clinically before and eight weeks after treatment. The patient and the analyst were not aware of the therapeutic content.

Participants/Inclusion and exclusion criteria
Inclusion criteria: male and female patients aged 18-65. Migraine with gastrointestinal symptoms. Patients are aware of the diagnosis of their illness, are Iranian and know the Persian language and available. Number of headache attacks at least 4 times a month with a duration of more than 30 minutes and severity of 4 or more (according to VAS). The patient's written consent form will be completed Exclusion criteria: The patient is diagnosed during or before pregnancy. Drug and alcohol abuse, or other traditional medicine, such as needles or herbal medicines

Intervention groups
The intervention group daily received 50 mg of Attrafil Minor and 200 mg of sodium valproate and the control group received daily 50 mg of placebo and 200 mg of sodium valproate.

Main outcome variables
The effect of Etrifel (a product of Iranian traditional medicine) on patients with migraine and gastrointestinal symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180416039331N1**
Registration date: **2018-08-24, 1397/06/02**
Registration timing: **retrospective**

Last update: **2018-08-24, 1397/06/02**
Update count: **0**

Registration date
2018-08-24, 1397/06/02

Registrant information

Name
hemaseh tavahen

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3724 0171

Email address
h.tavahen@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-07-22, 1395/05/01

Expected recruitment end date
2017-07-21, 1396/04/30

Actual recruitment start date
2016-07-22, 1395/05/01

Actual recruitment end date
2017-07-21, 1396/04/30

Trial completion date
empty

Scientific title

The effect of Etrifel (a product of Iranian traditional medicine) on patients with migraine and gastrointestinal symptoms

Public title

The effect of Etrifel (a product of Iranian traditional medicine) on patients with migraine and gastrointestinal symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Migraine sufferers with gastrointestinal symptoms (peptic ulcer) based on the diagnostic CRIs contained in authentic traditional medicine texts. Their headache has been confirmed by a clinical examination and diagnosis of a physician according to the IHS diagnostic criteria. Patients are aware of their diagnosis. Persian and know the Persian language and are available. Number of headache attacks at least 4 times a month with a duration of more than 30 minutes and severity of 4 or more (according to VAS). Patient's written consent.

Exclusion criteria:

Patient dissatisfaction with the continuation of the study. The patient is diagnosed during or before the pregnancy. Drug and alcohol abuse, or other traditional medicine, such as needles or herbal medicines

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **140**

Actual sample size reached: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly divided into two intervention and control groups. To randomize the number of participants, the envelopes with the letters A and B were used. Each participant selected an envelope. Group A was considered intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

After the patients were divided randomly into two groups of intervention and control, treatment was started. The patient and person who analyzed Data was unaware of the therapeutic content.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd University of Medical Sciences

Street address

Faculty of Traditional Medicine. Imam Khomeini street

City

Ardakan

Province

Yazd

Postal code

8951737915

Approval date

2016-12-26, 1395/10/06

Ethics committee reference number

IR.SSU.REC.1395.194

Health conditions studied

1

Description of health condition studied

بیماران میگرنی دارای سردرد مشارکتی معدی

ICD-10 code

G44

ICD-10 code description

Other headache syndromes

Primary outcomes

1

Description

Determine the rate of recovery from atrophil in migraine patients with gastroenterological symptoms

Timepoint

Before the intervention and 8 weeks after the intervention, the physician's global assessment was evaluated. Also, 4 weeks after the start of the intervention, a questionnaire was used to answer the treatment and possible complications.

Method of measurement

Notes and daily reports of patients

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Daily treatment with sodium

valproate 200 mg per day and Attrafilet Minor 50 mg before lunch and dinner

Category
Treatment - Drugs

2

Description
Control group: Daily treatment with sodium valproate 200 mg daily and placebo tablets 50 mg before lunch and dinner

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Specialized Clinic of Shahid Sadoughi Hospital in Yazd

Full name of responsible person
Majid Emtiazy

Street address
Shahid Sadoughi Hospital, Yazd. Yazd Safayee Shahid Ghandi Boulevard, Avicenna Street

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8951737915

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+98 35 3723 8915

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tebsonati@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

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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
Yazd University of Medical Sciences

Proportion provided by this source
90

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
Yazd University of Medical Sciences

Full name of responsible person
Majid Emtiazy

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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Faculty of Ardakan Traditional Medicine., Imam Khomeini street

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Person responsible for scientific inquiries

Contact

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Yazd University of Medical Sciences

Full name of responsible person
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Person responsible for updating data

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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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The data will be available to applicants upon identification and the patients will be provided at the discretion of the research and student deputy of the Ardakan Faculty of Medicine and three years after the publication of the article.
When the data will become available and for how long
Three years after the publication and publication of the article
To whom data/document is available
Specialists and researchers of traditional medicine and doctors
Under which criteria data/document could be used
After unidentifiable patients and patients at the discretion of the Research and Student Vice-Dean of the Faculty of Ardakan Traditional Medicine and three years after the publication of the paper for researchers and medical and health professionals
From where data/document is obtainable
E-mail the responsible person and, with the permission of the vice president of research and student of Yazd University of Medical Sciences
What processes are involved for a request to access data/document
Inform the person in charge and coordinate with the deputy research and student of Yazd University of Medical Sciences
Comments