

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of traditional medicine product Sofoofe Banafshe on the prevention of headaches in patients with migraine

Protocol summary

Summary

In this study, the effect of Persian traditional medicine product that is called Sofoof Banafshe is examined on migraine headaches. According to the traditional medicine resources, Sofoofe Banafshe includes Viola Odorata, Rosa Damascena and Corianderum Sativum powder with the same amount. This study is a double blind randomized clinical trial. This research is carried out at the clinic of the University of Medical Sciences on at least 86 patients with migraine. The diagnosis of migraine is confirmed by a neurologist based on the criteria of IHS (International Headache Society), and then the patients are divided into two groups. Patients in the intervention group are receiving propranolol 20 mg twice daily plus Sofoofe Banafshe capsules 500 mg three times a day for a month, and patients in the control group are receiving propranolol 20 mg twice daily plus placebo capsules 500 mg three times a day that included starch powder for a month. Variables, duration, severity and frequency of headaches per week is evaluated in the beginning and at the end of the second week and the fourth week by using a standard questionnaire and VAS criterion. SF36 quality of life questionnaire for patients is completing at the same time. finally the data are analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110830776N1**

Registration date: **2017-03-16, 1395/12/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-16, 1395/12/26

Registrant information

Name

Mohadese Kamali

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3211 2827

Email address

mohadesekamali0912@gmail.com

Recruitment status

Recruitment complete

Funding source

Assistance of Research center at Kerman University of Medical Sciences

Expected recruitment start date

2016-10-24, 1395/08/03

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of traditional medicine product Sofoofe Banafshe on the prevention of headaches in patients with migraine

Public title

The effect of Sofoofe Banafshe on migraines

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: confirmed the diagnosis of migraine according to the criteria of IHS; 15-45 age range; patients' awareness of their disease, no pregnancy or

lactation, without any other chronic diseases (heart, thyroid, hepatic, renal, neurologic, hypertension, diabetes, depression, etc.), experiencing at least four migraine attacks per month in the past few months
Exclusion criteria: dislike continuing cooperation, deciding for pregnancy or having a positive pregnancy test, experiencing non-migraine headaches; non-compliance with prescribed medication

Age

From **80 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomized double-blind study using four glass blocks

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kerman University of Medical Sciences

Street address

The Pardis of Kerman University of Medical Sciences,
Haft bagh Boulevard, Kerman

City

Kerman

Postal code

Approval date

2016-10-24, 1395/08/03

Ethics committee reference number

IR.KMU.AH.REC.1395.18

Health conditions studied

1

Description of health condition studied

migraine

ICD-10 code

G43

ICD-10 code description

Use additional external cause code (Chapter XX), if desired, to identify drug, if drug-induced.

Primary outcomes

1

Description

The number of migraine attacks per week

Timepoint

Two weeks and one month after intervention

Method of measurement

Self made questionnaire

2

Description

Severity of headache

Timepoint

Two weeks and one month after intervention

Method of measurement

VAS

3

Description

Frequency of headaches

Timepoint

Two weeks and one month after intervention

Method of measurement

Self made questionnaire

Secondary outcomes

1

Description

Quality of life

Timepoint

Two weeks and one month after intervention

Method of measurement

SF36

Intervention groups

1

Description

Patients in the control group receiving propranolol 20 mg twice daily plus placebo capsules 500 mg three times a day

Category

Treatment - Drugs

2

Description

Patients in the intervention group receiving propranolol 20 mg twice daily plus Sofoofe Banafshe capsuls 500 mg three times a day

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat clinic 4

Full name of responsible person

Mohadese Kamali

Street address

The end of Shahid rajaee street, Kerman

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The Research Center of Neurology Diseases, Kerman
University of Medical Sciences

Full name of responsible person

Mrs Zare

Street address

The Research Center of Neurology Diseases, Kosar
Boulevard, Kerman

City

Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

The Research Center of Neurology Diseases, Kerman
University of Medical Sciences

Proportion provided by this source

100

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

Kerman University of Medical Sciences, School of
Traditional Medicine

Full name of responsible person

Mohadese Kamali

Position

Postgraduate Persian Traditional Medicine

Other areas of specialty/work

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Person responsible for updating data

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Position

Postgraduate Traditional Medicine

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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