

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of Effects of Food Products Based on Traditional Persian Medicine on Hemorheology in Polycythemia

Protocol summary

Summary

The main aim of this study is to determine the effects of food products based on Traditional Persian Medicine on hemorheology in polycythemia. The study is a single blind randomized clinical trial on male patients with polycythemia aged 35-60 years without underlying disease, who have not received drug two weeks before entering the study. Those with a history of underlying disease or specific illness, the habit of smoking cigarettes, tobacco and narcotics, or food allergies are excluded. The total number of 40 patients is taken into account that randomly will be divided into two groups: intervention and control. The control group will be received only routine treatment (Phlebotomy) and intervention group will be used the diet in addition to standard treatment (Phlebotomy). The diet without sticky foods, matched two weeks before entering the study in both candidates, and will continue during the study period (6 weeks). The main intervention of this study is diet that is served as dinner and until two hours after, is no longer used for food. One's daily consumption is determined by BMI. The main outcome measure of the study is blood fluidity and related consequences outcome is laboratory tests included CBC, lipid profile, plasma fibrinogen, plasma osmolality and FBS. Candidates are tested at twice. The first time before entering the study and the second time after the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015111024993N1**

Registration date: **2015-12-04, 1394/09/13**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-12-04, 1394/09/13

Registrant information

Name

Hamideh Naghedi Baghdar

Name of organization / entity

Faculty of Iranian Traditional Medicine and Complementary of Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3855 2188

Email address

naghedih911@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology Mashhad University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Effects of Food Products Based on Traditional Persian Medicine on Hemorheology in Polycythemia

Public title

Effects of Food Products on Hemorheology

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: male patients; polycythemia without underlying disease; age range 35-60 years; no medication two weeks before entering the study
Exclusion criteria: food allergy; history of the underlying disease; history of experience disease; history of drug use before entering the study; Smoking a cigarette, tobacco and narcotics; lack of consent to continue the project; the possible incidence of side effects

Age

From **35 years** old to **60 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences
Administration, Building Qureshi, Daneshgah Ave.

City

Mashhad

Postal code

9138813944

Approval date

2015-11-07, 1394/08/16

Ethics committee reference number

IR.MUMS.REC.1394.496

Health conditions studied

1

Description of health condition studied

polycitemia

ICD-10 code

D75

ICD-10 code description

Other diseases of blood and blood-forming organs

Primary outcomes

1

Description

Blood fluidity

Timepoint

Baseline, the end of the study

Method of measurement

R/S-CC Plus Coaxial Cylinder Rheometer Brookfield-type

Secondary outcomes

1

Description

CBC

Timepoint

Baseline, the end of the study

Method of measurement

Laboratory blood test

2

Description

Lipid profile

Timepoint

Baseline, the end of the study

Method of measurement

Laboratory blood test

3

Description

Plasma fibrinogen

Timepoint

Baseline, the end of the study

Method of measurement

Laboratory blood test

4

Description

Plasma osmolality

Timepoint

Baseline, the end of the study

Method of measurement

Laboratory blood test

5

Description

FBS

Timepoint

Baseline, the end of the study

Method of measurement

Laboratory blood test

Intervention groups

1

Description

Control group: phlebotomy only in the beginning of the study

Category

Treatment - Other

2

Description

Intervention group: diet for 6 weeks in addition to phlebotomy at baseline. This diet is served as dinner and until two hours after, is no longer used for food. One's daily consumption is determined by BMI in such a way that people with a BMI less than 20, 350 grams daily, people with a BMI between 20 and 30 daily 400 grams and people with a BMI greater than 30 received daily 450 grams of this food. Ingredients in the preparation of the foods weighed and packed with recipes based on the amount determined, as it is for the patients. During the study period is 6 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Easar health clinics affiliated to hospital of Imam Reza

Full name of responsible person

Hamideh Naghedi Baghdar

Street address

Faculty of Iranian Traditional Medicine and Complementary, Opposite the Mehran sports hall, East Razi Ave.

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research and Technology Vice-Chancellory of Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Research and Technology Vice-Chancellory of Mashhad University of Medical Sciences, Building Qureshi, Daneshgah Ave.

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research and Technology Vice-Chancellory of Mashhad 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Iranian Traditional Medicine and Complementary of Mashhad University of Medical Sciences

Full name of responsible person

Seyyed Mohammad Nazari

Position

Assistant Professor

Other areas of specialty/work

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tim@mums.ac.ir Nazarim@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Iranian Traditional Medicine and Complementary of Mashhad University of Medical Sciences

Full name of responsible person

Hamideh Naghedi Baghdar

Position

PhD student of Iranian Traditional Medicine and Complementary

Other areas of specialty/work**Street address**

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Web page address**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