Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A study of the effects of saffron petals' aqueous extract on lipid profile in patients with dyslipidemia

Protocol summary

Summary

The aim of this study is to investigate the effect of saffron petals on dyslipidemic disorders among individuals with dyslipidemia. A total of 50 patients with dyslipidemia (HDL≤40; LDL≥130; TG≥200; total cholesterol≥200 mg/dl), ranging from 30 to 60 years, irrespective of gender, will be selected by convenience sampling method and included upon providing written consent. Recruitment will take place in the office of a cardiovascular disease specialist. Then, the selected participants will be randomly allocated into placebo and saffron groups using random digits table. Additionally, the study is triple-blind, meaning that the patient, the data collector, and the statistical analyst are unaware of the type of intervention throughout the study. The patients in the intervention and control groups will use, respectively, one pill of saffron and placebo orally at a dose of 30 mg/kg per body weight on a daily basis for four weeks after one or another main meal of the day. Before and 28 days after the intervention, patient blood samples will be taken to measure HDL, LDL, TG, and total cholesterol.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016083017756N4**
Registration date: **2016-09-15, 1395/06/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-09-15, 1395/06/25

Registrant information

Name

Mohammad Bagher Roozgar

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3239 5680

Email address

mbroozgar@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study of the effects of saffron petals' aqueous extract on lipid profile in patients with dyslipidemia

Public title

An inquiry into saffron's effects on dyslipidemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with lipid disorders (HDL≤40; LDL≥130; TG≥200; total cholesterol≥200 mg/dl); Not receiving antidyslipidemic drugs; age from 30 to 60 years; no history of stroke or heart surgery; lack of genetic dyslipidemic disease; provision of informed consent. Exclusion criteria: use of antidyslipidemic drugs during the study; incidence of myocardial infarction or

heart surgery during the study; occurrence of unexpected circumstances for the participant such as an accident, death, etc.; failure to use saffron or placebo pills during the study, even for a single day

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Birjand University of Medical Sciences

Street address
Ghaffari St.

City
Birjand

Postal code

Approval date
2015-11-22, 1394/09/01

Ethics committee reference number
Ir.bums.1394.54

Health conditions studied

1

Description of health condition studied
Dyslipidemia

ICD-10 code
e78.1

ICD-10 code description
Pure hyperglyceridaemia

Primary outcomes

1

Description
Triglyceride

Timepoint
Before and 28 days after intervention

Method of measurement
Pars Azmoon kit and Autoanalyzer

2

Description
Total cholesterol

Timepoint
Before and 28 days after intervention

Method of measurement
Pars Azmoon kit and Autoanalyzer

3

Description
LDL

Timepoint
Before and 28 days after intervention

Method of measurement
Pars Azmoon kit and Autoanalyzer

4

Description
HDL

Timepoint
Before and 28 days after intervention

Method of measurement
Pars Azmoon kit and Autoanalyzer

Secondary outcomes

1

Description
Liver enzymes

Timepoint
Before and 28 days after intervention

Method of measurement
Pars Azmoon kit and Autoanalyzer

Intervention groups

1

Description
Intervention Group: A total of 25 patients with dyslipidemia will be selected by convenience sampling method based on inclusion criteria and assigned into this group using random digits table. Saffron petal tablets will be made by the Faculty of Pharmacy, Kerman University of Medical Sciences, at a dose of 30 mg/kg body weight. Tablets will be given blindly to the patients so that they will take a pill daily after a main meal for 28 days. Before

and 28 days after the intervention, patient blood samples will be taken to measure the related variables.

Category

Treatment - Drugs

2

Description

Control Group: A total of 25 patients with dyslipidemia will be selected by convenience sampling method based on inclusion criteria and assigned into this group using random digits table. Placebo tablets will be made by the Faculty of Pharmacy, Kerman University of Medical Sciences, at a dose of 30 mg/kg body weight. Tablets will be given blindly to the patients so that they will take a pill daily after a main meal for 28 days. Before and 28 days after the intervention, patient blood samples will be taken to measure the related variables.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Office of Cardiovascular Disease Specialist

Full name of responsible person

Street address

No. 10, Third Alley, Taleghani St.,

City

Birjand,

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellery for Research and Technology, Birjand University of Medical Sciences

Full name of responsible person

Dr Tooba Kazemi

Street address

Ghaffari St.,

City

Birjand,

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-Chancellery for Research and Technology, Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Dr Reyhane Hoshyar

Position

Faculty Member

Other areas of specialty/work

Street address

Ghaffari St.,

City

Birjand,

Postal code

9717853577

Phone

+98 938 258 8299

Fax

Email

reyhaneh.houshyar@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Reyhane Hoshyar

Position

Assistant Professor

Other areas of specialty/work

Street address

Ghaffari St.,

City

Birjand,

Postal code

9717853577

Phone

+98 938 258 8299

Fax

Email

reyhaneh.houshyar@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Mohammad Bagher Roozgar

Position

PhD Candidate in Translation Studies

Other areas of specialty/work

Street address

Ghaffari St.,

City

Birjand,

Postal code

9717853577

Phone

+98 56 3239 5680

Fax

Email

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