

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 ($HDL \leq 40$; $LDL \geq 130$; $TG \geq 200$; 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

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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 ($HDL \leq 40$; $LDL \geq 130$; $TG \geq 200$; 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

lr.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

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Assistant Professor

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Full name of responsible person

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Position

PhD Candidate in Translation Studies

Other areas of specialty/work

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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