Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Study of the effect of extract of Common barberry (Berberis vulgaris L.) on oxidative stress in type 2 diabetic patients

Protocol summary

Summary

The purpose of this study is to evaluate the effect of extract of Common barberry on oxidative stress in patients with type 2 diabetes mellitus in a randomized clinical trial design. 72 patients covered by Shahroud Diabetes Society according to inclusion criteria such as patient over the age 50 year old and common diabetes drugs usage and exclusion criteria such as patients with renal, liver diseases or non-compliance with treatment will randomly divide into three groups, intervention group 1: patients with type 2diabetes (24 women) that ingest common barberry extract, intervention group 2: patients with type 2 diabetes (24 women) which will not undergo treatment with Common barberry extract and control group: 24 women without type 2 diabetes which will not undergo any treatment, After and before 8 weeks of continuous treatment, blood sample will collect from patients to measure oxidative stress.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011221412N3**
Registration date: **2016-05-22, 1395/03/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-22, 1395/03/02

Registrant information

Name

Hamid Kalalian Moghadam

Name of organization / entity

Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahroud University of Medical Sciences

Expected recruitment start date

2015-02-18, 1393/11/29

Expected recruitment end date

2015-05-05, 1394/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of extract of Common barberry (Berberis vulgaris L.) on oxidative stress in type 2 diabetic patients

Public title

Effect of Common barberry extract in type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: female gender over the age of 50 years old; HbA1c levels equal or less than 10%; common diabetes drugs usage (Metformin and Glibenclamide); patients with triglyceride. Exclusion criteria: patients with cardiovascular; renal; liver; thyroid diseases; infections; allergies; angina; the regular use of NSAIDs (Non-Steroid Anti Inflammatory Drugs); warfarin; alcohol; herbal tea; dietary supplements; insulin injection.

Age
From **50 years** old to **70 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomization will be performed by the Randlist software and every patient will be entered into 2 intervention groups and control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahroud University of Medical Sciences
Street address
Shahroud University of Medical Sciences, Haftom Tir Square
City
Shahroud
Postal code
Approval date
2015-09-29, 1394/07/07
Ethics committee reference number
IR.SHMU.REC.113

Health conditions studied

1

Description of health condition studied
Diabetes mellitus type 2
ICD-10 code
E11
ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Fasting Plasma Glucose
Timepoint
After and before 8 weeks of continuous treatment
Method of measurement
Blood test by using a Pars Azmoon biochemical kit (Pars Azmoon Co., Tehran, Iran).

2

Description
Triglycerides
Timepoint
After and before 8 weeks of continuous treatment
Method of measurement
Blood test by using a Pars Azmoon biochemical kit (Pars Azmoon Co., Tehran, Iran).

3

Description
Serum superoxide dismutase
Timepoint
After and before 8 weeks of continuous treatment
Method of measurement
Blood test by using a Pars Azmoon biochemical kit (Pars Azmoon Co., Tehran, Iran).

4

Description
Nitric Oxide
Timepoint
After and before 8 weeks of continuous treatment
Method of measurement
Blood test by using a Pars Azmoon biochemical kit (Pars Azmoon Co., Tehran, Iran).

5

Description
Serum glutamic-pyruvic transaminase
Timepoint
After and before 8 weeks of continuous treatment
Method of measurement
Blood test by using a Pars Azmoon biochemical kit (Pars Azmoon Co., Tehran, Iran).

6

Description
Serum glutamic- oxaloacetic transaminase
Timepoint
After and before 8 weeks of continuous treatment
Method of measurement
Blood test by using a Pars Azmoon biochemical kit (Pars Azmoon Co., Tehran, Iran).

7

Description
High-density lipoprotein
Timepoint
After and before 8 weeks of continuous treatment
Method of measurement
Blood test by using a Pars Azmoon biochemical kit (Pars Azmoon Co., Tehran, Iran).

8

Description
Low-density lipoprotein
Timepoint
After and before 8 weeks of continuous treatment
Method of measurement
Blood test by using a Pars Azmoon biochemical kit (Pars Azmoon Co., Tehran, Iran).

Secondary outcomes

empty

Intervention groups

1

Description
intervention group 1: patients with type 2 diabetes (24 women) which will use common diabetes drugs.
Category
Treatment - Drugs

2

Description
intervention group 2: patients with type 2 diabetes (24 women) that ingest 5cc of common barberry extract during 8 weeks.
Category
Treatment - Drugs

3

Description
control group: 24 women without type 2 diabetes which will not undergo any treatment
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Dr. Hamid Kalalian Moghadam
Street address
Imam Hossein Hospital, Imam Street
City
Shahroud

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahroud University of Medical Sciences
Full name of responsible person
Dr. Hamid Kalalian Moghadam
Street address
Shahroud University of Medical Sciences, Haftom Tir Square, Shahroud
City
Shahroud
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Dr. Hamid Kalalian Moghadam
Position
Assistant Professor of Physiology,Shahroud University of Medical Sciences
Other areas of specialty/work
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Person responsible for scientific inquiries

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Assistant Professor of Physiology,Shahroud University of Medical Sciences

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Person responsible for updating data

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Dr. Hamid Kalalian Moghadam

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Assistant Professor of Physiology,Shahroud University of Medical Sciences

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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