Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Safety profile and metabolic effects of Rosa damascena extract in patients with type II diabetes and healthy volunteers: A triple blind and acarbose controlled phase II and III clinical trial

Protocol summary

Summary

Background: The worldwide increase in type 2 diabetes mellitus is becoming a major health concern. Rosa damascena extract had shown to have an intensive non-competitive inhibitory effect on α-glucosidase in an animal study. We aimed to assess the safety and efficacy of Rosa damascena (RD) Mill on blood sugar in diabetic and normal population. Methods: Subjects were 12 men and 20 women aged 18 to 75 years with type II diabetes of at least 6 months duration who were drug naive as diabetic group; and 7 men and 21 women aged between 18 and 75 years non diabetic volunteers as healthy group.Inclusion criteria in diabetic patients were a body-mass index between 25 and 40 kg/m2, HbA1C between 6.5% and 8% and fasting blood sugar less than 200mg/dl. Exclusion criteria were pregnancy, breast feeding, renal or hepatic failure and uncontrolled or complicated diabetes.In a triple-blind, placebo and acarbose-controlled randomized trial, we randomly allocated diabetic patients and normal volunteers to 100 mg acarbose, 200 or 400 mg RD-methanolic extract or placebo daily. We followed up the participants for 15 days regarding the possible side effects and any changes in laboratory.parameters. Analyses were done by intention to treat.

General information

Acronym

Rosa damascena extract in patients with type II diabetes

IRCT registration information

IRCT registration number: **IRCT138809221774N2**
Registration date: **2012-07-21, 1391/04/31**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-07-21, 1391/04/31

Registrant information

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Name of organization / entity
Kerman University of Medical Science
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Recruitment status

Recruitment complete

Funding source

kerman university of medical sciences

Expected recruitment start date

2009-03-20, 1387/12/30

Expected recruitment end date

2010-03-20, 1388/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety profile and metabolic effects of Rosa damascena extract in patients with type II diabetes and healthy volunteers: A triple blind and acarbose controlled phase II and III clinical trial

Public title

Safety profile and metabolic effects of Rosa damascena extract in patients with type II diabetes and healthy

volunteers: A triple blind and acarbose controlled phase II and III clinical trial

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria in diabetic patients were a body-mass index between 25 and 40 kg/m2, HbA1C between 6.5% and 8% and fasting blood sugar less than 200mg/dl. Exclusion criteria were pregnancy, breast feeding, renal or hepatic failure and uncontrolled or complicated diabetes

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
kerman university of medical sciences

Street address
kerman university of medical sciences

City
kerman

Postal code

Approval date
2010-01-01, 1388/10/11

Ethics committee reference number
88.71

Health conditions studied

1

Description of health condition studied
diabetes mellitus

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Blood Sugar 2 Hours Postprandial

Timepoint
Days 0-8-15 after start of the internention

Method of measurement
mg/dl-analysor

2

Description
Fasting Blood Sugar

Timepoint
Days 0-8-15 after start of the internention

Method of measurement
mg/dl-analysor

3

Description
fructosamine

Timepoint
Days 0-15 after start of the intervention

Method of measurement
mg/dl-chromatography

Secondary outcomes

1

Description
urine analysis

Timepoint
days 0-8-15 ofter intervention

Method of measurement
microscopic & macroscopic - laboratory analyzer

2

Description
Complete Blood Count

Timepoint
Days 0-8-15 ofter intervention

Method of measurement
laboratory analyzer

3

Description
Haemoglobin A1C

Timepoint
days 0 of the study

Method of measurement
percent - nycocard reader2

4

Description
liver fanctional tests
Timepoint
days 0-8-15 ofter intervention
Method of measurement
mg/dl-laboratory analyzer

Intervention groups

1

Description
first group: swallowing of 200 mg Rosa damascena (RD)-methanolic extract daily for 15 days
Category
Treatment - Drugs

2

Description
second group:swallowing of 400 mg RD-methanolic extract daily for 15 days
Category
Treatment - Drugs

3

Description
third group: swallowing of placebo pills daily for 15 days
Category
Placebo

4

Description
forth group: swallowing of 100 mg acarbose daily for 15 days with lunch meal
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour hospital ,kerman Iran
Full name of responsible person
Dr. Mahboubeh Mashyekhi
Street address
Afzalipour hospital ,kerman Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kerman University of Medical Sciences PhYsiology resaerch center of
Full name of responsible person
Dr.Hamid Najafi pour
Street address
Physiology research center, Ebne sina Ave, Jahad Blvd, Kerman, Iran
City
kerman
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, Kerman University of Medical Sciences PhYsiology resaerch center of
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
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http://www.kmu.ac.ir/sitewizard/admin/wizard/Default.Aspx?PageId=3089

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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