Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of extract of rosa canina fruit on orthostatic hypotension in people with type 2 diabetes

Protocol summary

Study aim
Determining the effectiveness of Nestern on orthostatic hypotension in people with type 2 diabetes

Design
A clinical trial with a control group, double-blind, randomized, phase 3 on 60 patients. For randomization, simple randomization method is used through Random allocation software version 2.0.

Settings and conduct
This study will be conducted in Yazd diabetes center on patients with type 2 diabetes and orthostatic hypotension. One group will receive placebo and one group will receive capsules containing Rosa canola plant extract based on the random allocation list prepared by the statistician. Drug and placebo are marked in similar packages with letters A and B, and only the pharmaceutical company knows which package is drug or placebo, and the researcher, statistical consultant, patients, and supervisor do not know about this.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age over 18 years; suffering from type 2 diabetes; Suffering from orthostatic hypotension based on internal specialist's diagnosis. Exclusion criteria: recent stroke or heart attack, having heart rhythm disorders, uncontrolled blood pressure, end-stage renal disease (ESRD), neuromuscular disease, heart failure (CHF), HA1C level more than 9, GFR level less than 30, people who are treated with prazosin and tamsulosin, unwillingness to treatment

Intervention groups
People with type 2 diabetes who have orthostatic hypotension

Main outcome variables
Improvement of orthostatic hypotension in patients with type 2 diabetes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240726062545N1**
Registration date: **2024-08-03, 1403/05/13**
Registration timing: **prospective**

Last update: **2024-08-03, 1403/05/13**
Update count: **0**

Registration date
2024-08-03, 1403/05/13

Registrant information

Name
Morvarid Salamati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3822 4000

Email address
m.salamati78@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-05, 1403/06/15

Expected recruitment end date
2024-10-21, 1403/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of extract of rosa canina fruit on orthostatic hypotension in people with type 2 diabetes

Public title
Investigating the effect of extract of rosa canina fruit on orthostatic hypotension
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age above 18 years Suffering from type 2 diabetes Suffering from orthostatic hypotension based on internal specialist's diagnosis
Exclusion criteria:
Recent stroke or heart attack Having heart rhythm disorders uncontrolled blood pressure end-stage renal disease (ESRD) neuromuscular disease heart failure (CHF) HA1C level greater than 9 GFR less than 30 People who are treated with prazosin and tamsulosin
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, one of the groups is denoted by the letter A and the other group by the letter B. Then, the random allocation list is prepared by using the simple randomization method and through the Random allocation software version 2.0 by the statistical consultant. In this way, it is determined which of the types of drug packages each patient will receive based on the order of entry into the study(A or B). The drug and placebo are packed in similar containers by the drug supplier and labeled with the letters A and B. Which letter indicates which intervention is determined by the drug supplier during labeling, and Until the completion of the study, no one other than her/him will be informed about this issue.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patient: Capsules containing medicine and placebo are completely similar in terms of shape, color and packaging. Due to the fact that rosa canina has a pleasant smell and the drug and placebo can be distinguished by the smell, so somerosa canina essential oil will be added to the content of the placebo so that they are almost similar in smell. Principal Investigator: The concerned resident will receive identical sealed medication packages marked with the letter A or B and will not be informed of which drug/placebo is contained in each medication package. Statistical consultant: She prepares the randomization list for two letters A and B, but she will not know which letter represents the intervention and which represents the control.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics commitee of School of Medicine - Shahid Sadoughi University of Medical Sciences
Street address
Ebne sina Blvd ,Shahid Sadoughi Hospital
City
Yazd
Province
Yazd
Postal code
8915887857
Approval date
2024-07-06, 1403/04/16
Ethics committee reference number
IR.SSU.MEDICINE.REC.1403.042

Health conditions studied

1

Description of health condition studied
orthostatic hypotension
ICD-10 code
I95.1
ICD-10 code description
Orthostatic hypotension

Primary outcomes

1

Description
orthostatic hypotension
Timepoint
Measurement of orthostatic hypotension at the beginning of the study and one month after the consumption of the rosa canina extract.
Method of measurement
Use of sphygmomanometer

2

Description

Orthostatic Intolerance* Questionnaire (OIQ) score

Timepoint

Measurement of Orthostatic Intolerance* Questionnaire (OIQ) score at the beginning of the study and one month after consumption of Rosa canina extract.

Method of measurement

Orthostatic Intolerance* Questionnaire (OIQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to health recommendations such as drinking large amounts of fluids and increasing salt intake and following a diet, a 500 mg capsule containing water extract powder of Rosa canina with ID (voucher number I.SE.009), which is prepared as a capsule It is prepared from a pharmaceutical company affiliated with the Hellal Ahmar , it is used twice a day for 4 weeks. The standardization of the drug is based on total polyphenol as gallic acid.

Category

Treatment - Drugs

2

Description

Control group: In addition to health recommendations, such as drinking large amounts of fluids and increasing salt intake and following a diet, 500 mg placebo capsules containing starch powder and 1% Rosa canina essential oil are used every 12 hours for a month.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Center for Diabetes

Full name of responsible person

Morvarid Salamati

Street address

Ebnesina Blvd, Shafid sadoughi hospital

City

Yazd

Province

Yazd

Postal code

8915887857

Phone

+98 910 230 9239

Email

m.salamti78@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Morvarid Salamati

Street address

Ebn Sina Blvd, Shahid Sadoughi Hospital

City

Yazd

Province

Yazd

Postal code

8915887857

Phone

+98 910 230 9239

Email

m.salamati78@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Morvarid Salamati

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Ebn Sina Blvd, Shahid Sadoughi Hospital

City

Yazd

Province

Yazd

Postal code

8915887857

Phone

0003538224000

Email

m.salamati78@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Morvarid Salamati

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Ebn Sina Blvd, Shahid Sadoughi Hospital

City

Yazd

Province

Yazd

Postal code

8915887857

Phone

000353822400

Email

m.salamati78@ gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Morvarid Salamati

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Ebn Sina Blvd, Shahid Sadoughi Hospital

City

Yazd

Province

Yazd

Postal code

8915887857

Phone

0003538224000

Email

m.salamati78@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available