

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Grape seed extract on Fasting blood glucose, Lipid profile and Blood pressure in patients with type 2 diabetes mellitus; A randomized double blind clinical trial.

Protocol summary

Study aim

Determination of the effect of Grape seed on fasting blood glucose level, lipid profile and blood pressure in patients with type 2 diabetes mellitus

Design

Clinical trial with control group, with parallel groups, double-blind, randomization, phase 3 on 80 patients.

Settings and conduct

Samples of patients with type 2 diabetes who are being treated with oral hypoglycemic drugs and referred to the diabetes clinic of Golestan hospital in Ahvaz on an outpatient basis They will be selected. All patients are asked to continue their previous medications to control their blood sugar, fat, and blood pressure during treatment, according to their doctor, and should not change their dose during the study. Patients are divided into two groups using a randomized list (40 patients in each group). Group A in addition to antidiabetic drugs, Grape seed herbal pills and group B in addition to antidiabetic drugs will be given placebo tablets (containing starch).

Participants/Inclusion and exclusion criteria

Age 25_80 years, HBA1C 7%_8. 5%, Fasting blood sugar between 126-200 mg / dL, The diagnosis of diabetes is less than 10 years, Patients should use only oral hypoglycemic drugs, BMI <35 Exclusion criteria Pregnancy-breastfeeding, Insulin therapy, Significant renal and hepatic impairment (overt renal failure if CLCr <30 and severe hepatic impairment if ALT or AST greater than 100)

Intervention groups

The intervention group consumed two grape seed tablets daily and the control group consumed two placebo tablets (containing starch) daily for 30 days.

Main outcome variables

Fasting blood sugar, TG, HDL, LDL, Chol, systolic blood pressure and diastolic blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210612051544N1**

Registration date: **2021-08-16, 1400/05/25**

Registration timing: **prospective**

Last update: **2021-08-16, 1400/05/25**

Update count: **0**

Registration date

2021-08-16, 1400/05/25

Registrant information

Name

Marzieh Alavifar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Grape seed extract on Fasting blood glucose, Lipid profile and Blood pressure in patients with type 2 diabetes mellitus; A randomized double blind clinical trial.

Public title

The effect of Grape seed on the control of blood sugar, blood lipids and blood pressure.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 25_80 years HbA1C 7%_8/5% FBS 126_200 mg/dl
Diabetes diagnosis period less than 10 years Patients use only oral hypoglycemic drugs BMI less than 35

Exclusion criteria:

Breastfeeding_ pregnancy Insulin therapy Obvious renal and hepatic insufficiency { Obvious renal failure with CLCr less than 30 and obvious hepatic insufficiency with ALT or AST more than 100 }

Age

From **25 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the randomization method of permutation blocks. In this two-group clinical trial, the size of blocks 4, 6 and 8 is considered (in this method, the number of people assigned to each group in the blocks is equal). For concealment, we use concealment allocation, which is the method used to execute a random sequence on study participants, so that the assigned group is not known before the individual is assigned. Using opaque, sealed, numbered sequentially sealed non-transparent envelopes (envelopes opaque, sealed, numbered sequentially) in which in this method each random sequence is recorded on a card and the cards are placed in the envelopes respectively. Are placed. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed. Randomization list using PLAN procedure in the software SAS is generated.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients do not know the type of drug (placebo or herbal pill ..). The patient evaluator is also not aware of the type of treatment assigned to patients so that patients can be evaluated without any bias. Therefore, this study will be performed based on the two-blind method.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences and He

Street address

Golestan Blvd., Shahrestaneshgahi, Esfand St., Ahvaz Jundishapur University of Medical Sciences, Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences and Health Services, Ground Floor

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Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2021-04-13, 1400/01/24

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1400.012

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes mellitus

ICD-10 code

diabetes

ICD-10 code description

diabetes mellitus

Primary outcomes**1****Description**

TG

Timepoint

At the beginning of the intervention and 30 days after taking Grape seed

Method of measurement

Blood test

2

Description

Cholesterol

Timepoint

At the beginning of the intervention and 30 days after taking Grape seed

Method of measurement

Blood test

3

Description

HDL

Timepoint

At the beginning of the intervention and 30 days after taking Grape seed

Method of measurement

Blood test

4

Description

LDL

Timepoint

At the beginning of the intervention and 30 days after taking Grape seed

Method of measurement

Blood test

5

Description

FBS

Timepoint

At the beginning of the intervention and 30 days after taking Grape seed

Method of measurement

Blood test

6

Description

Systolic blood pressure

Timepoint

At the beginning of the intervention and 30 days after taking Grape seed

Method of measurement

Sphygmomanometer

7

Description

Diastolic blood pressure

Timepoint

At the beginning of the intervention and 30 days after taking Grape seed

Method of measurement

Sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Grape seed extract, grape seed extract 263.2 mg, two tablets daily, duration of use 30 days, Shari Pharmaceutical Supplement Company. All patients are asked to continue their previous medications to control their blood sugar, fat, and blood pressure during the study period, according to their doctor, and should not change their dose during the study.

Category

Treatment - Drugs

2

Description

Control group: placebo tablets (containing starch), 263.2 mg, two daily, duration of use for 30 days, Shari Pharmaceutical Supplement Company. All patients are asked to continue their previous medications to control their blood sugar, fat, and blood pressure during the study period, according to their doctor, and should not change their dose during the study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized and sub-specialized clinic of Golestan Hospital in Ahvaz

Full name of responsible person

Mehrnoosh Zakerkish

Street address

Golestan dormitory - specialized and sub-specialized clinic of Golestan hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadi Moghadam

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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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