

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Study of the effects of *Salvadora persica* extract on blood sugar and lipid profile in diabetic patients (type2)

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Investigation of the effect of oral consumption of *Salvadora persica* extract on the signs and symptoms of diabetes and other systemic symptoms

Last update: **2021-10-20, 1400/07/28**

Update count: **0**

Registration date

2021-10-20, 1400/07/28

Design

A clinical trial with a control group, with parallel groups, triple-blind, randomized, phase 2, on 120 patients in 3 groups, for 8 weeks, will be treated with oral drug syrup (150 or 300 mg) or placebo twice a day, 5 cc each time. A table of random numbers will be used for randomization.

Registrant information

Name

Akram Izadikhah najafabadi

Name of organization / entity

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Iran (Islamic Republic of)

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Settings and conduct

This study will be performed on patients with active records in the diabetes clinic of Sedigheh Tahereh Medical Center in Isfahan.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having type 2 diabetes in the last 10 years; Age 60-30 years; $5/6 \geq \text{HbA1c} \geq 5/7$; Patient consent to participate in the project. Exclusion criteria: Pregnancy and lactation; Consumption of injectable drugs for lowering blood sugar (types of injectable insulin) and oral drugs from the category of sulfinyl urea; Kidney or liver failure.

Expected recruitment start date

2021-10-08, 1400/07/16

Expected recruitment end date

2022-10-08, 1401/07/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Three groups of patients: drug group with a dose of 300 mg per day and drug group with a dose of 600 mg per day and placebo group

Scientific title

Study of the effects of *Salvadora persica* extract on blood sugar and lipid profile in diabetic patients (type2)

Main outcome variables

BMI ; FBS ; HbA1c ; Homa IR ; TC ; TG ; LDL ; HDL ; AST ; ALT ; Constipation, urinary, skin, gastrointestinal and neurological symptoms

Public title

Study of the effects of *Salvadora persica* extract on blood sugar and lipid profile in diabetic patients (type2)

Purpose

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210906052392N1**

Registration date: **2021-10-20, 1400/07/28**

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having type 2 diabetes in the last 10 years Age 60-30 years HbA1c between 5.6 to 7.5 Patient consent to participate in the project

Exclusion criteria:
Pregnancy or breastfeeding Use of injectable hypoglycemic drugs (injectable insulin) and oral sulfonylureas Renal or liver failure

Age
From **35 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling is done by easy sampling method. In this study, random allocation will be done by Stratified Permuted Blocked Randomization (by age-sex subgroups). In this method, eligible individuals with inclusion criteria will be selected and then they will be randomly divided into three groups of interventions and controls using three blocks. Finally, a table with 4 columns for men over 50, men under 50, women over 50, women under 50, each column in the rows containing the letters A, B, C randomly for three study groups. At the beginning of the patients' arrival, if the entry conditions are met, according to their age and gender, it is placed in a column and according to the English letters, it is placed in one of the study groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study, neither the patient nor the researcher nor the analyzer knew in which intervention group or placebo. Patients are divided into three groups A, B, C. Drugs are also in three categories A, B, C that are assigned to patients. The analyzer does not know which group of patients will receive medication or placebo until the end of the analysis of the results.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee Isfahan University of Medical Sciences, School of Medicine

Street address

Hezar Jerib Street

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Isfahan

Postal code

81746-73461

Approval date

2021-09-14, 1400/06/23

Ethics committee reference number

IR.MUI.MED.REC.1400.489

Health conditions studied

1

Description of health condition studied

Diabetes melitus type 2

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fasting blood sugar

Timepoint

Before the start of the study, the end of 8 weeks of intervention

Method of measurement

medical lab

2

Description

triglyceride, Cholesterol, HDL

Timepoint

Before the start of the study, the end of 8 weeks of intervention

Method of measurement

medical lab

3

Description

Homa IR

Timepoint

Before the start of the study, the end of 8 weeks of

intervention
Method of measurement
medical lab

4

Description
AST, ALT
Timepoint
Before the start of the study, the end of 8 weeks of intervention
Method of measurement
medical lab

5

Description
HbA1c
Timepoint
Before the start of the study, the end of 8 weeks of intervention
Method of measurement
medical lab

6

Description
BMI
Timepoint
Before the start of the study, the end of 8 weeks of intervention
Method of measurement
medical lab

7

Description
Constipation score
Timepoint
Before the start of the study, the end of 8 weeks of intervention
Method of measurement
Using the WEXNER questionnaire

8

Description
Gastrointestinal symptoms score
Timepoint
Before the start of the study, the end of 8 weeks of intervention
Method of measurement
Researcher-made gastrointestinal symptoms questionnaire

9

Description
Urinary symptoms score
Timepoint
Before the start of the study, the end of 8 weeks of intervention
Method of measurement

Researcher-made questionnaire on urinary symptoms

10

Description
Score of skin symptoms
Timepoint
Before the start of the study, the end of 8 weeks of intervention
Method of measurement
Researcher-made skin symptoms questionnaire

11

Description
Nervous Symptoms Score
Timepoint
Before the start of the study, the end of 8 weeks of intervention
Method of measurement
Researcher-made neurological symptoms questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group 1: Consumption of medicine for 8 weeks, syrup containing *S. persica* extract in a dose of 150 mg twice a day
Category
Treatment - Drugs

2

Description
Intervention group: Group 2: Consumption of medicine for 8 weeks, syrup containing *S. persica* extract in a dose of 300 mg twice a day
Category
Treatment - Drugs

3

Description
Control group: Take a placebo for 8 weeks, a syrup containing the same inactive substance twice a day
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Sedigheh Tahereh Educational, Therapeutic and Research Complex
Full name of responsible person

Akram Izadikhah

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Akram Izadikhah

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Hezar Jarib Streets

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Akram Izadikhah

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Data confidentiality

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