

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Study of the Effect of Hydroalcoholic Extract of Lavandula Officinalis on Some Biochemical Factors in Blood and Urine in Diabetes.

Protocol summary

Study aim

Study of the effect of hydroalcoholic extract of lavandula officinalis on some biochemical factors in blood and urine in diabetic patients

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2-3 on 80 patients. Random allocation software was used for randomization.

Settings and conduct

The present study was performed in Imam Ali Clinic affiliated to Shahrekord University of Medical Sciences in 1398.

Participants/Inclusion and exclusion criteria

Diabetic patients between the ages of 30 and 60 years without significant concomitant underlying disease and no insulin intake

Intervention groups

The drug group received two lavender capsules daily for 2 months and the control group received two placebo capsules daily for 2 months. Tests checked twice before and after taking the medication.

Main outcome variables

FBS, lipid profile, BUN, Cr, HbA1C, urine protein and urine sugar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200826048534N1**

Registration date: **2020-09-12, 1399/06/22**

Registration timing: **retrospective**

Last update: **2020-09-12, 1399/06/22**

Update count: **0**

Registration date

2020-09-12, 1399/06/22

Registrant information

Name

Sanaz Hojatyar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3263 2006

Email address

sanazhojatyar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

2019-05-22, 1398/03/01

Actual recruitment end date

2019-08-06, 1398/05/15

Trial completion date

2019-10-23, 1398/08/01

Scientific title

Study of the Effect of Hydroalcoholic Extract of Lavandula Officinalis on Some Biochemical Factors in Blood and Urine in Diabetes.

Public title

Effect of Lavandula Officinalis in treatment of diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of diabetes Patients aged 30 to 60 years
Fasting blood sugar ≥ 126 mg / dl Intravenous blood serum glucose 200 mg/dl, 2 hours after ingestion of 75 g of oral glucose Not receiving insulin HbA1C from 7 to 8.5
Diagnosis of diabetes is less than 10 years Use only oral

antihyperglycemic drugs(Metformin,Glibenclamide)
Exclusion criteria:
Smoking Chronic Cardiovascular Diseases Chronic Kidney Disease Triglycerides more than 500 Pregnancy Taking Anticoagulants (except Aspirin) Chronic Liver Diseases except Fatty Liver Advanced Diabetic Retinopathy Kidney Failure Heart Failure Hemorrhagic Stroke

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **80**

Actual sample size reached: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 80 diabetic patients referred to Imam Ali Clinic in Shahrekord according to the number of patients referred (diagnosis number) and grouping A and B (which was not clear to patients and the person responsible for patient selection , which group of drugs and which placebo) through Random Allocation statistical software related to simple randomization method was obtained and entered into each of the relevant groups (with random numbers Computer software that divided the numbers 1 to 80 into simple groups A and B by simple randomization. It was determined which number of patient be in which group A or B.)

Blinding (investigator's opinion)

Double blinded

Blinding description

None of the patients knew in which group (drug or control) they were. The person responsible for patient selection was also unaware of which of A or B group was the drug or placebo group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Shahrekord, Kashani Blvd., University Headquarters, Building No. 2

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

۸۸۱۵۷۱۳۴۷۱

Approval date

2018-05-26, 1397/03/05

Ethics committee reference number

IR.SKUMS.REC.1397.044

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E10-E14

ICD-10 code description

Diabetes mellitus

Primary outcomes

1

Description

Fasting blood sugar

Timepoint

At the beginning of the study and 2 months after consumption of drugs

Method of measurement

With special kits by an autoanalyzer system

2

Description

HbA1C

Timepoint

At the beginning of the study and 2 months after consumption of drugs

Method of measurement

With special kits by an autoanalyzer system

3

Description

Cholestrol

Timepoint

At the beginning of the study and 2 months after consumption of drugs

Method of measurement

With special kits by an autoanalyzer system

4

Description

Very low density lipoprotein

Timepoint

At the beginning of the study and 2 months after

consumption of drugs
Method of measurement
With special kits by an autoanalyzer system

5

Description
Low density lipoprotein
Timepoint
At the beginning of the study and 2 months after consumption of drugs
Method of measurement
With special kits by an autoanalyzer system

6

Description
High density lipoprotein
Timepoint
At the beginning of the study and 2 months after consumption of drugs
Method of measurement
With special kits by an autoanalyzer system

7

Description
Triglyceride
Timepoint
At the beginning of the study and 2 months after consumption of drugs
Method of measurement
With special kits by an autoanalyzer system

8

Description
Alanine transaminase
Timepoint
At the beginning of the study and 2 months after consumption of drugs
Method of measurement
With special kits by an autoanalyzer system

9

Description
Aspartate aminotransferase
Timepoint
At the beginning of the study and 2 months after consumption of drugs
Method of measurement
With special kits by an autoanalyzer system

10

Description
Blood urea nitrogen
Timepoint
At the beginning of the study and 2 months after consumption of drugs
Method of measurement
With special kits by an autoanalyzer system

11

Description
Creatinine
Timepoint
At the beginning of the study and 2 months after consumption of drugs
Method of measurement
With special kits by an autoanalyzer system

12

Description
Urine sugar
Timepoint
At the beginning of the study and 2 months after consumption of drugs
Method of measurement
With urine strip dip stick

13

Description
Urine protein
Timepoint
At the beginning of the study and 2 months after consumption of drugs
Method of measurement
With urine strip dip stick

14

Description
Body mass index
Timepoint
At the beginning of the study and 2 months after consumption of drugs
Method of measurement
It was measured and calculated with a tape measure and Ska scale (weight in kilograms divided by height to the power of 2 in square meters).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 40 diabetic patients who, in addition to routine medications used by diabetic patients (Metformin, Glibenclamide), received 2, 500 mg capsules containing Lavender extract daily, 2 times in the morning and at night.
Category
Treatment - Drugs

2

Description
Control group: 40 diabetic patients who, in addition to

routine medications(Metformin,Glibenclamide) used by diabetic patients, received 2 placebo capsules twice daily before meals.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Ali Clinic

Full name of responsible person

Sanaz Hojatyar

Street address

Shahrekord, Shariati Boulevard, Imam Ali Specialized Clinic

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

۸۸۱۵۷۱۳۴۷۱

Phone

+98 38 3224 2696

Email

info@skums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Mehraban Sadeghi

Street address

Shahrekord, Kashani Blvd., University Headquarters, Building No. 2

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

۸۸۱۵۷۱۳۴۷۱

Phone

+98 38 3334 2414

Email

vcrt@skums.ac.ir

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

Yes

Title of funding source

Shahre-kord 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**

Shahre-kord University of Medical Sciences

Full name of responsible person

Leila Mahmudnia

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Shahrekord, Rahmatieh, Shahrekord University of Medical Sciences

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8158166356

Phone

+98 38 3333 9940

Email

mahmudnia.L@skums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Leila Mahmudnia

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Shahrekord, Rahmatieh, Shahrekord University of Medical Sciences

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8158166356

Phone

+98 38 3333 9940

Email

mahmudnia.L@skums.ac.ir

Person responsible for updating data

mahmudnia.L@skums.ac.ir

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Leila Mahmudnia

Position

Assistant professor

Latest degree

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Shahrekord, Rahmatieh, Shahrekord University of
Medical Sciences

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8158166356

Phone

+98 38 3333 9940

Email

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