

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

A Comparison Between the Effect of Sugar Heal and Metformin on Fasting Blood Sugar (FBS), 2-hours Postprandial Sugar, Low density lipoprotein and Urea in Pre-diabetic Patients.

Protocol summary

Study aim

Comparison of the effectiveness of Sugar Heal and metformin on the parameters of fasting blood sugar, glucose tolerance test, low density lipoprotein and blood urea in pre-diabetic patients

Design

In this phase 3 study with two parallel groups, 136 patients with pre-diabetic condition will be randomized and quadruple blocks will be divided into intervention and control groups, and in this regard, they will receive the intervention or control drug. This study will be a double-blind trial.

Settings and conduct

This study will be performed in Baqiyatallah Hospital in Tehran and patients and researchers will be unaware of the content of each group's drug.

Participants/Inclusion and exclusion criteria

Patients whose pre-diabetic conditions have been confirmed according to scientific criteria. Be over 18 years old. without liver and kidney failure, without pregnancy and lactation, without sensitivity to herbal medicines and not taking other drugs that affect blood sugar. Absence of proliferative or neoplastic retinopathy

Intervention groups

The study has two groups in which, the intervention group will use Sugarheal 1000mg drug and in the control group patients will take metformin 500mg.

Main outcome variables

In patients participating in this study, the rate of change in fasting glucose, the rate of change in blood urea, the rate of change in body lipids, glucose tolerance test and changes in insulin hormone will be measured.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210914052480N1**

Registration date: **2022-07-06, 1401/04/15**

Registration timing: **prospective**

Last update: **2022-07-06, 1401/04/15**

Update count: **0**

Registration date

2022-07-06, 1401/04/15

Registrant information

Name

Alireza Soleymanitabar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison Between the Effect of Sugar Heal and Metformin on Fasting Blood Sugar (FBS), 2-hours

Postprandial Sugar, Low density lipoprotein and Urea in Pre-diabetic Patients.

Public title
effect of sugarheal in patients with prediabetic situation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
patients with confirmed prediabetic situation over 18 years old
Exclusion criteria:
patients with Chronic renal failure patients with Chronic liver failure patients with active pneumonia patients with Proliferative or active neoplastic retinopathy pregnancy or lactation History of allergy to herbal medicines Taking other drugs that affect blood sugar

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Randomization would be done with 4 units blocks

Blinding (investigator's opinion)
Double blinded

Blinding description
Medications are received in similar packages with only one code written on them. By the end of the study, none of the researchers and patients knew the contents of the drug capsules

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Baqiyatallah Hospital
Street address
mollasadra st.
City

tehran
Province
Tehran
Postal code
1435916471
Approval date
2022-05-21, 1401/02/31
Ethics committee reference number
IR.BMSU.BAQ.REC.1401.019

Health conditions studied

1

Description of health condition studied
pre-diabetic condition
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
fasting blood glucose change
Timepoint
3 months
Method of measurement
blood test

2

Description
change in serum lipids(LDL, HDL, cholesterol, TG)
Timepoint
3 months
Method of measurement
blood test

3

Description
changes in insulin hormone level
Timepoint
3 months
Method of measurement
blood test

4

Description
changes in blood BUN level
Timepoint
3 months
Method of measurement
blood test

5

Description
changes in GTT test
Timepoint

3 months
Method of measurement
blood test

6

Description
changes in Hb A1c level
Timepoint
3 months
Method of measurement
blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Sugarheal medicinal composition from Samanik company: The amount of extract of each plant in one gram is calculated according to the amount of consumption of each plant per day. Therefore, in each gram of the extract, the weight of Capparis Spinosa extract 170 mg, Rosa canina 225 mg, Securigera securidaca 170 mg, Silymarin 65 mg, Urtica dioica 170 mg, Trigonella foenum-graecum 115 mg and Vaccinium arctostaphylos 85 mg will be mixed together. 1000 mg of the extract mixture will be poured into two 500 mg long base capsules. The prepared capsule is packed in a box of 60 pieces. Patients will receive two doses from this medicine with their meals for 3 months and then second checkup will be done.

Category
Treatment - Drugs

2

Description
Control group: This group will receive metformin which is the standard protocol nowadays 500 mg twice a day with their meals for three months. These capsules are exactly as same as the capsules of intervention group. After 3 months the second checkup will be done.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان بقیه الله
Full name of responsible person
محمد هیئت
Street address
mollasadra St. Vanak Tehran
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mohamad.heiat@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Mohamad heiat
Street address
baqiyatallah hospital, mollasadra St. Tehran, Iran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Samanik company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Mohammad heiat
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work

Medical Biology
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Alireza Soleymanitabar
Position
Student
Latest degree
A Level or less

Other areas of specialty/work
General Practitioner
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asoleimanitabar21@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

the data would be sent without any personal information of patients

When the data will become available and for how long

after data gathering

To whom data/document is available

Only people with relevant permissions to use confidential information

Under which criteria data/document could be used

The data can be used for statistical analysis and re-examination

From where data/document is obtainable

mohamad heiat Phone no. +98 936 687 6929

What processes are involved for a request to access data/document

After calling or sending an email, the data will be sent if the applicant is valid

Comments