

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 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)

###### Phone

+98 21 8755 4364

###### Email address

stu.soleymanitabar@bmsu.ac.ir

##### 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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mohamad.heiat@gmail.com  
**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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mollasadra st. Vanak Tehran  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Position**  
Associate professor  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Bagheiat-allah University of Medical Sciences  
**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