

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of glucoherb and metformin on glycemic indexes in prediabetics patients

Protocol summary

Registration timing: **retrospective**

Study aim

Comparison of the glucoherb efficacy with metformin on glycemic indices and glycosylated hemoglobin in prediabetes patients referring to Imam Ali Diabetic Center

Last update: **2019-10-19, 1398/07/27**

Update count: **0**

Registration date

2019-10-19, 1398/07/27

Design

This study is a double blind clinical trial phase 3. 72 patients were randomly assigned to two intervention groups. Intervention group 1: Metformin tablets orally 500 mg daily and Intervention group 2: Glucoherb tablets (herbal medicine of Barij essence). After four months, patients' blood glucose levels are checked again

Registrant information

Name

Abolghasem sharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Settings and conduct

72 Patients studied in the diabetes center of Shahrekord. For blinding, drugs are taken out from their main boxes and put in boxes without name that has written just letters A or B and they are the name of groups and drugs are given to the patients by one of the nurses in terms of the groups.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: not consuming anti-diabetes and insulin medications, corticosteroids, and multivitamins, not being pregnant or breast-feeding, cooperating in the study, and having prediabetes symptoms. Exclusion criteria: not continue the study

Expected recruitment start date

2017-06-21, 1396/03/31

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

2017-06-30, 1396/04/09

Actual recruitment end date

2018-12-21, 1397/09/30

Trial completion date

2019-02-28, 1397/12/09

Intervention groups

Intervention group 1: Metformin tablets taken orally 500 mg daily Intervention group 2: Oral glucohydrate tablets (herbal medicine of Barij essence).

Main outcome variables

Blood suger level

Scientific title

The effect of glucoherb and metformin on glycemic indexes in prediabetics patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190125042486N2**

Registration date: **2019-10-19, 1398/07/27**

Public title

The effect of glucoherb and metformin on glycemic indexes in prediabetics patients

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

They do not consume tobacco. They do not consume alcohol. Patients who do not take anti-diabetes and insulin medications. Patients who are not pregnant or breast-feeding. In the recent 3 months, multivitamin, antioxidant and Omega 3 have not received. Patients who have not kidney, liver, thyroid and parathyroid, gastrointestinal and heart disease and cancer. Medicines like corticosteroids that have an effect on blood glucose are not consumed They would like to participate in the project. Patients who are recognized with prediabetes symptoms.

Exclusion criteria:

Patients cancel continuing the study.

Age

From **1 day** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **72**

Actual sample size reached: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling was random allocation, which patients randomly selected as B or A envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blinding included the investigator and patients. For not having aware of patients, medications were taken out from the package and placed in cans written with letters A or B. For not having aware of investigator, the medications were administered or injected to the patients by nurses.

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Shahrekord University of Medical

Sciences

Street address

Kashani street

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8814646885

Approval date

2019-03-04, 1397/12/13

Ethics committee reference number

IR.SKUMS.REC.1397.266

Health conditions studied

1

Description of health condition studied

diabetes mellitus

ICD-10 code

E10-E14

ICD-10 code description

With other specified complications

Primary outcomes

1

Description

glycemic indexes

Timepoint

at the end of 12th week

Method of measurement

The checklist contained the name and characteristics of the patients together with the treatment group.

Checklists of FBS, BS2PP, HBA1C

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1:take metformin tablets orally 500 mg orally

Category

Treatment - Drugs

2

Description

Intervention group 2: take Glucherb tablets (herbal medicine of Barij essence)

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Diabetic Center

Full name of responsible person

Rahil Riyahi

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Parastar Avenue

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Email

riahi.r@skums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Kamal Solati

Street address

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solati_k@yahoo.com

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

Iman Izadi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Rahil Reyahi

Position

Assistant professor

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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parastar Avenue

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Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Abolghasem Sharifi

Position

in employment

Latest degree

Master

Other areas of specialty/work

Social Services

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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

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Title : The comparison of glucoherb efficacy with metformin on glyceimic indices and glycosylated hemoglobin in prediabetes diseases referring to imam ali diabetic center

When the data will become available and for how long

2019

To whom data/document is available

Rahil Reyahi

Under which criteria data/document could be used

ethics Committee

From where data/document is obtainable

Deputy of Research and Technology

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

A request to Deputy of Research and Technology

Comments

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