Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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

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

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.

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

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

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190125042486N2**
Registration date: **2019-10-19, 1398/07/27**
Registration timing: **retrospective**

Last update: **2019-10-19, 1398/07/27**
Update count: **0**

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

Registrant information
Name
Abolghasem sharifi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 38 3333 0061
Email address
gh_sh_fr51@yahoo.com

Recruitment status
Recruitment complete

Funding source

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

Scientific title
The effect of glucoherb and metformin on glycemic indixes in prediabetics patients

Public title
The effect of glucoherb and metformin on glycemic indixes 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, antioxide 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 indixes

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
Street address
Parastar Avenue
City
Shahrekord
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Chahar-Mahal-va-Bakhtiari
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8814646885
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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
Kashani street
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8814646885
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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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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Rahil Reyahi
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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
Street address
kashani Street
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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 glycemic 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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