

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of Glucoherb (herbal drug) in comparison with metformin on decreasing insulin resistance in prediabetic children with obesity

Protocol summary

Study aim

Find alternatives to improve glycemic index status instead of metformin

Design

In this study, designing the Zelen design, individuals will be randomly assigned into two groups of control and intervention and then informed consent will be obtained. They know and people in the control group know that they use routine treatment. Patients do not become blind to the drug they receive

Settings and conduct

Patients referred to Sanandaj Endocrinology Clinic aged 15 to 25 years were studied according to inclusion and exclusion criteria, divided by random numbers into test and control groups, and obtaining informed consent from patients and parents with Zelen's design without blinding design. . At the beginning of the study, the demographic variables of fasting blood sugar and insulin and HOMA index are measured. Three months after taking treatment, fasting insulin and blood sugar levels and HOMA index are measured again. Ready packs containing herbal capsules for one group and metformin for the other group were given to patients. The capsule was instructed that the research unit should consume one capsule daily after lunch. Patients should be referred if they have any side effects.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Overweight and obesity Exclusion criteria: lack of kidney or liver disease Do not take drugs such as corticosteroids that cause elevated glucose levels. Other medicines to control blood sugar, Type 2 diabetes based on fasting blood sugar, HbA1C criteria and clinical symptoms

Intervention groups

Obese or overweight patients aged 15 to 25 years in two groups receiving metformin and group receiving glucoherb

Main outcome variables

Fasting blood Glucose levels glycosylated hemoglobin level Insulin Resistance Index (Homa Index)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141208020249N6**

Registration date: **2020-09-07, 1399/06/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-07, 1399/06/17**

Update count: **0**

Registration date

2020-09-07, 1399/06/17

Registrant information

Name

Behzad Khalafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3344 9697

Email address

khalafi.behzad70@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Glucoherb (herbal drug) in comparison with metformin on decreasing insulin resistance in prediabetic children with obesity

Public title

Effect of Glucoherb (herbal drug) in comparison with metformin on decreasing insulin resistance

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Overweight Obesity Lack of Documented Diabetes

Exclusion criteria:

Documented Diabetes Taking affect glucose level drugs like corticosteroids Liver disorders kidney disorders Use other blood glucose control drugs

Age

From **15 years** old to **25 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals were randomly assigned to test and control groups based on the random numbers obtained from the randomized Excel program.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kurdistan University of Medical Sciences

Street address

pasdaran Blvd, opposite Shadi Hotel, Kurdistan University of Medical Sciences, Sanandaj,

Management of Medical Researches and Information.

POB 6617713446

City

sanandaj

Province

Kurdistan

Postal code

6617713446

Approval date

2019-11-12, 1398/08/21

Ethics committee reference number

IR.MUK.REC.1398.189

Health conditions studied**1****Description of health condition studied**

Obesity and Overweight

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes**1****Description**

Fasting blood Glucose level

Timepoint

Start and end of the study

Method of measurement

Enzymatic method of hexokinase

2**Description**

Glycosylated hemoglobin

Timepoint

Start and end of the study

Method of measurement

HPLC method

3**Description**

Insulin Resistance index

Timepoint

Start and end of the study

Method of measurement

Using the HOMA Index formula

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Daily one Glucoherb Capsule

Category

Treatment - Drugs

2

Description

Control group: Daily 500 mg Metformin

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Asadollah Fathollah pour

Street address

Vakil Crossroad, Besat Hospital, Department of pediatric

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Sanandaj

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2

Recruitment center

Name of recruitment center

Asadollah Fathollah pour office

Full name of responsible person

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Mehr Doctors Building, Yagmoori Alley, Pasdaran Blve

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Afshin Maleki

Street address

Sanandaj, Kurdistan University of Medical Sciences, opposite Shadi Hotel, Kurdistan University of Medical Science, POB 6617713446 Management of medical research and information

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maleki43@yahoo.com

Grant name

Pediatric Residency program

Grant code / Reference number

IR.MUK.REC.1398.189

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Mohsen Akheshteh

Position

Pediatric resident

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

Sanandaj University of Medical Sciences

Full name of responsible person

Asadollah Fathollah Pour

Position

Associated professor of Pediatric Endocrinology

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Behzad Khalafi

Position

Research Associate / Researcher Soldier - General Physician of Kurdistan University of Medical Sciences

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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

Yes - There is 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

All data is from the proposal, raw data and project reports

When the data will become available and for how long

داده ها 6 ماه پس از انتشار به مدت دو سال قابلیت دسترسی از طریق تقاضا از سیستم قانونی را دارد

To whom data/document is available

All persons will be able to access the Kurdistan University of Medical Sciences's request to the Kurdistan University of Medical Sciences.

Under which criteria data/document could be used

For legal issues and the need to use data in future studies

From where data/document is obtainable

Asadollah Fathollah pour

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

After submitting a request to the Kurdistan Research and Technology Dept. of Science and Technology, a call for submission is given.

Comments