Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The role of Gingko biloba extract as monotherapy in improving insulin resistance, BMI, VAI, leptin and level in patients with metabolic syndrome: A pilot comparative study with metformin

Protocol summary

Study aim

The present study was designed to evaluate the effects of Ginkgo biloba extract on the insulin resistance, visceral adiposity index and BMI in patients with metabolic syndrome.

Design

The study is randomized double blind clinical trial at the Center of Diabetes and Endocrine Glands, Directory of Health/ Sulaimani city. Fifty patients were recruited from public hospitals and private clinics according to the selection criteria. Simple randomization of the patients was done and they were allocated into two groups (25 patients each) as follow: Group A received Metformin (500 mg tablet) and group B received GKB extract (120 mg/capsule)group; both treatments received daily single dose and for three months. Patients follow up was performed on monthly bases to ensure patient compliance.

Settings and conduct

The study is randomized double blind clinical trial at the Center of Diabetes and Endocrine Glands, Directory of Health/ Sulaimani city. The duration of the trial was three months. The blinded people were : participants, investigator, and outcome assessor and the blinding was done by a third party.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Newly diagnosed metabolic syndrome patients- both sexes Exclusion criteria : Pregnancy, ischemic heart disease, cardiac arrhythmias, glucose-6-phosphate dehydrogenase (G6PD) deficiency, bleeding disorders, seizures, and known hypersensitivity to any component of the trial drugs (GKB extract and Metformin).

Intervention groups

metformin group and Ginkgo biloba group

Main outcome variables

Fasing blood sugar, HbA1C, insulin level, Leptin level, Triglyceride, HDL, insulin resistance, visceral adiposity index and BMI.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200803048285N1**
Registration date: **2020-08-25, 1399/06/04**
Registration timing: **retrospective**

Last update: **2020-08-25, 1399/06/04**
Update count: **0**

Registration date

2020-08-25, 1399/06/04

Registrant information

Name

Tavga Aziz

Name of organization / entity

University of Sulaimani

Country

Iraq

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-01, 1399/02/12

Expected recruitment end date

2020-06-01, 1399/03/12

Actual recruitment start date

2020-05-01, 1399/02/12

Actual recruitment end date
2020-06-01, 1399/03/12
Trial completion date
2020-09-01, 1399/06/11

Scientific title
The role of Gingko biloba extract as monotherapy in improving insulin resistance, BMI, VAI, leptin and level in patients with metabolic syndrome: A pilot comparative study with metformin

Public title
effects of gingko biloba on the outcomes of metabolic syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
newly diagnosed as Metabolic syndrome both sexes
Exclusion criteria:
pregnancy ischemic heart disease G6PD Deficiency bleeding disorders seizures allergy to the medications used in this trial
Age
From **25 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**
Actual sample size reached: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization of the individuals done using a shuffled deck of cards. 50 cards containing numbers starting from 1 to 50 and even numbers represent group A (Metformin) and odd numbers represent group B (Ginkgo biloba extract).
Blinding (investigator's opinion)
Double blinded
Blinding description
The participants were not aware about the treatment (metformin or ginkgo biloba). The researcher and the outcome assessor also were not aware about the exact treatment they only had information of group A and B till the end of the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethical committee of the University of Sulaimani
Street address
Daniel Metran Street
City
Sulaymaniyah
Postal code
46001
Approval date
2019-12-01, 1398/09/10
Ethics committee reference number
507/1024

Health conditions studied

1

Description of health condition studied
metabolic syndrome
ICD-10 code
E88.81
ICD-10 code description
Metabolic syndrome

Primary outcomes

1

Description
Glycemic status is the main outcome of the study and this include: fasting blood sugar, HbA1C, Insulin level, Insulin resistance,
Timepoint
At the time of first enrollment of the patient (zero time) and at the end of the study (after 90 days) of intervention
Method of measurement
The patients will be advised to be fasted for 12 hr and measurment of glycemic status will be performed by taking blood samples at the zero time and after 90 days of intervention and using lab kit to measure fasting blood glucose, HbA1c and insulin level. Insulin resistance will be calculated using HOMA-IR.

2

Description
Body mass index (BMI)
Timepoint
At the time of first enrollment of the patient (zero time) and at the end of the study (after 90 days) of intervention
Method of measurement
BMI is calculated by using the following formula: weight (kg) / [height (m)]2. Height and weight are measured by an electronic scale and a wall-mounted stadiometer

3

Description
Visceral adiposity index (VAI): The VAI is an empirical mathematical model, which is gender specific and based on simple anthropometric, BMI and waist circumference (WC) and functional parameters (TG and HDL-c), is an indicator of body fat distribution and function.
Timepoint
At the time of first enrollment of the patient (zero time) and at the end of the study (after 90 days) of intervention
Method of measurement
Calculation of VAI is according to the formula given by Amato et al.24 The formula is a linear equation derived by extrapolation from the relationship between BMI and WC in a healthy normal/overweight population. Distribution mode of adipose tissue was corrected for TG and HDL-c levels to determine the VAI as follows: Female VAI = (WC/36.58 + (1.89 × BMI)) × (TG/0.81) × (1.52/HDL) Male VAI = (WC/39.68 + (1.88 × BMI)) × (TG/1.03) × (1.31/HDL) Where WC is expressed in cm, BMI in kg/m2, TG in mmol/L, and HDL in mmol/L.

Secondary outcomes

1

Description
Leptin: It is one of the vital hormones expressed by the adipose tissue, and it has a critical role in regulating food consumption and energy production through its action on the hypothalamic nuclei
Timepoint
At the time of first enrollment of the patients (zero time) and at the end of the study (after 90 days of intervention).
Method of measurement
The measurement of leptin level will be done using Elisa lab kit specific for leptin measurement

2

Description
Safety profile of ginkgo biloba on the hematological markers: Hb(g/dl), Hct (%), RBC, WBC and palelets counts
Timepoint
At the time of first enrollment of the patients (zero time) and at the end of the study (after 90 days of intervention).
Method of measurement
The hematological markers: Hb(g/dl), Hct (%), RBC, WBC and palelets counts are measured using lab kits.

Intervention groups

1

Description
Intervention group (metformin group): In this group the patients received 500 mg metformin as a single dose orally for 90 days
Category
Treatment - Drugs

2

Description
Intervention group (Ginkgo biloba extract treated group): In this group the patients received 120 mg Ginkgo biloba extractas a single dose orally for 90 days
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Center of diabetes and endocrine diseases
Full name of responsible person
Dr Taha Othman Mahwi
Street address
Qrga street
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mahwi63@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
College of Pharmacy / University of Sulaimani
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Web page address
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
College of Pharmacy / University of Sulaimani
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
University of Sulaimani - College of Pharmacy

Full name of responsible person
Tavga Ahmed Aziz

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Pharmacology and Toxicology

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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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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
Only the name of the patients will not be shared other wise all data will be available

When the data will become available and for how long

The data will be available after the end of the study and publishing the research article and the data will be available on request

To whom data/document is available

For all researchers in academic institutions and in in other research centers

Under which criteria data/document could be used

for further researches about using alternative medicine in Metabolic Syndrome

From where data/document is obtainable

contact the following : Tavga Ahmed Aziz College of Pharmacy University of Sulaimani tavga.aziz@univsul.edu.iq 009647701523544

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

By e-mail and/or phone

Comments