

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The effect of diabetosit supplement (extract of nettle leaf and olive leaf) on blood glucose and lipid profile in type 2 diabetic patients

Protocol summary

Study aim

The effect of Urtica Dioica leaf and Olive Leaf Composition on lowering of Blood Glucose and Lipids in Type II Diabetic Patients

Design

A randomized, double-blind, placebo-controlled phase 3 clinical trial with 30 patients in each group.

Settings and conduct

The study subjects will be non-insulin dependent type 2 diabetic patients from a private clinic and diabetes clinic of Razi hospital in Rasht, Guilan. All patients in the control group or the intervention group will be followed for two months. Fasting glucose, postprandial glucose, lipids, and glycosylated hemoglobin are measured before and the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria 1-Patients over 30 years old 2-Non-dependent -Insulin type 2 diabetes mellitus patients 3- Under treatment with oral glucose-lowering drugs
Exclusion Criteria 1- History of underlying heart Disease 2- Kidney Disease 3- Thyroid Disease 4- liver disease 5- Pregnancy or lactation 6- Insulin -dependent patients

Intervention groups

The intervention group will receive the herbal supplement in addition to the usual treatment. The control group will receive placebo in addition to the usual treatment.

Main outcome variables

Fasting blood sugar; Postprandial blood glucose; HBA1C; Serum lipids

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190728044350N1**

Registration date: **2019-09-08, 1398/06/17**

Registration timing: **prospective**

Last update: **2019-09-08, 1398/06/17**

Update count: **0**

Registration date

2019-09-08, 1398/06/17

Registrant information

Name

Zahra Mohtasham-Amiri

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3331 1472

Email address

mohtashamaz@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-07, 1398/07/15

Expected recruitment end date

2019-12-06, 1398/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of diabetosit supplement (extract of nettle leaf and olive leaf) on blood glucose and lipid profile in type 2 diabetic patients

Public title

"Effect of Diabetosit herbal supplement in treatment of Diabetes"

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Over 30 years old Under treatment with oral glucose-lowering drugs

Exclusion criteria:

Insulin dependent patients History of heart disease or myocardial infarction History of asthma and allergy to nettle Hepatic insufficiency Pregnancy or lactation Thyroid diseases Severe infection Renal Insufficiency

Age

From **30 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who have medical records in the clinic and hospital and eligible for participating in the study are numbered and then a random number will be found by using the "Randomizer Research" software. This number is multiply by the number of samples(30). This process is repeated to reach the total sample size in the study. We can make a block with two in one block (block size is two) with two possible sequences of AB to assign sample numbers equally to each group. Above the consent form of the participants are labeled letters A or B in each group (n = 30) and these forms are provided to the secretaries of clinics. An independent nurse prepares syrups with "drug A" and "drug B" and put them into boxes according to the allocation orders. These syrups cannot be distinguished because they contain the same colored liquid with the same volume. Syrups will be given to them after the consent is signed based on the letter mentioned above the form by clinic nurse. Secretaries, clinical caregivers and nurses have no information about the type of syrups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Main medication and placebo are coded in order to be double-blind. Clinical providers, clinicians and patients are unaware of the type of drug being offered. Both of case and control groups, will receive placebo or herbal oral solution as 20 ml pre-meal for 8 weeks in addition to the usual treatment. . Only in analyzing data each group will be identified.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

No 8, Nasim Ave, Deilaman Blvd, Golsar, Rasht

City

Rasht

Province

Guilan

Postal code

4163545851

Approval date

2019-06-26, 1398/04/05

Ethics committee reference number

IR.GUMS.REC.1398.153

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Percentage of patients with Fasting blood sugar lower than 140 mg/dl

Timepoint

At baseline and 8 weeks after study

Method of measurement

Biochemical tests are carried out by the Selectra autoanalyser. Total cholesterol will be measured enzymatically using cholesterol esterase and cholesterol oxidase. HDL-C is measured after deposition of lipoproteins containing APO-B by phosphotungstic acid with the same enzymatic method of total cholesterol. Triglycerides will be carried out enzymatically using glycerol phosphate oxidase. LDL-C is measured in serum samples with triglyceride levels equal or less than 400 mg / dl using the Freidwald formula.

Secondary outcomes

1

Description

Blood pressure

Timepoint

At baseline and 8 weeks after

Method of measurement

Using mercury sphygmomanometer

Intervention groups

1

Description

Receiving herbal supplement Diabetosit made by Yasin Teb Gostar Co for 8 weeks, 20 cc, three times a day before meals. Ingredients of 1 Liter Diabetosit Supplement : 100 grams of dried nettle leaves extract and 100 grams of dried olive leaves extract in 1 liter olive oil.

Category

Treatment - Other

2

Description

Control group: will receive the usual treatment in addition to a solution similar to diabetosit (new supplement) as the placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic of Razi Hospital

Full name of responsible person

Zahra Abbasi Ranjbar

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2

Recruitment center

Name of recruitment center

Ofogh prevention and Health Center

Full name of responsible person

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Pasargad Building, Bastani Shoar Square, Golipour Blvd

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zmamiri2000@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mostafa Golshekan

Street address

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Guilan

Postal code

4134645971

Phone

+98 13 3323 0078

Email

mostafa.golshekan@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Yasin Sina-Gostar

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

Rasht University of Medical Sciences

Full name of responsible person

Zahra Mohtasham-Amiri

Position

Full Professor

Latest degree
Specialist
Other areas of specialty/work
Public Health/Community Medicine
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Samaneh Shirkouhi
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data is shared anonymous.

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

Academic researchers, pharmacists, and industry leaders

Under which criteria data/document could be used

Analysis of side effects

From where data/document is obtainable

Zahra Mohtasham-Amiri, P.O Box 3381 Rasht, Iran
mohtashamaz@yahoo.com

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

The letter should state the reason and usage for the request. It will be answered as soon as possible.

Comments