Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 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
Street address
Sardare Jangal Blvd, Rasht
City
Rasht
Province
Guilan
Postal code
4163545851
Phone
+98 13 3355 0028
Email
dr.abbasdarjani@yahoo.com

2

Recruitment center
Name of recruitment center
Ofogh prevention and Health Center
Full name of responsible person
Zahra Mohtasham-Amiri
Street address
Pasargad Building, Bastani Shoar Squre, Golipour Blvd
City
Rasht
Province
Guilan
Postal code
4163545851
Phone
+98 13 3313 1862
Fax
+98 13 3313 1864
Email
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
Malekpour Ave, Shariatei St
City
Rasht
Province
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
Street address
Poursina Hospital, Parastar Ave,Namjoo St,
City
Rasht
Province
Guilan
Postal code
4163545851
Phone
+98 13 3336 8773
Email
mohtashamaz@yahoo.com

Person responsible for scientific 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
Street address
No , Nasim Abv, Deilaman Blvd, Golsar St
City
Rasht
Province
Guilan
Postal code
4163545851
Phone
+98 13 3375 9480
Email
zmamiri2000@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Samaneh Shirkouhi
Position
Researcher
Latest degree
Master
Other areas of specialty/work
Public Health
Street address
Guilan Road Trauma Research Center, Poursina Hospital, Namjoo St,
City
Rasht
Province
Guilan
Postal code
4163545851
Phone
+98 13 3331 1472
Email
s.shirkoohi@yahoo.com

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