Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study on the Efficacy of Aerial Parts Extract of Urtica dioica L. in Treatment of Type 2 Diabetic Patients

Protocol summary

Summary

Objective: Study on efficacy of aerial parts extract of Urtica dioica L. in treatment of type 2 diabetic patients. Study population: type 2 diabetic patients of the outpatient clinic in the Qom Kamkar and Shahid Beheshti hospitals. Inclusion criteria: type 2 diabetic patients, patients aged 40 to 60 years, patients with fasting serum glucose level above 200 mg/dl, patients with blood glycosylated hemoglobin level above 8 percent, patients who despite using a combination of oral synthetic antidiabetic drugs, their blood glucose level is not within the normal range and thus need insulin injection but refuse to inject insulin. Exclusion criteria:patients with cardiac, renal, hepatic diseases, concomitant infections, pregnant women, women planning pregnancy, breast-feeding women. The intervention: Nettle aerial parts extract is administered to a group of 30 patients at the dose of one 500 mg capsule every 8 hours in addition to the oral synthetic antidiabetic drugs for 3 months and placebo is administered to another group of 30 patients every 8 hours in addition to the oral synthetic antidiabetic drugs for 3 months. At the end of the study, the blood glucose, glycosylated hemoglobin, creatinin, liver enzymes including SGOT and SGPT levels in the drug group and the placebo group are determined and compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809022288N2**
Registration date: **2009-12-12, 1388/09/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2009-12-12, 1388/09/21

Registrant information

Name
Saeed Kianbakht
Name of organization / entity
Iranian Academic Center for Education, Culture and Research Institute of Medicinal Plants
Country
Iran (Islamic Republic of)
Phone
+98 26147640109
Email address
kianbakht@imp.ac.ir

Recruitment status

Recruitment complete

Funding source

(1) Institute of Medicinal Plants affiliated with the ACECR
(2) Qom University of Medical Sciences

Expected recruitment start date

2007-12-22, 1386/10/01

Expected recruitment end date

2010-12-22, 1389/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study on the Efficacy of Aerial Parts Extract of Urtica dioica L. in Treatment of Type 2 Diabetic Patients

Public title

Study on the efficacy of nettle in the treatment of type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: type 2 diabetic patients, patients aged 40 to 60 years, patients with fasting serum glucose level above 200 mg/dl, patients with blood glycosylated hemoglobin level above 8 percent, patients who despite using a combination of oral synthetic antidiabetic drugs, their blood glucose level is not within the normal range and thus need insulin injection but refuse to inject insulin. Exclusion criteria:patients with cardiac, renal, hepatic diseases, concomitant infections, pregnant women, women planning pregnancy, breast-feeding women.

Age
From **40 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Double-blind placebo-controlled randomized clinical trial

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Qom University of Medical Sciences

Street address
Golestan Alley, Number 2 Alley, Moallem Jonubi Avenue

City
Qom

Postal code
3713645612

Approval date
empty

Ethics committee reference number
39257

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus (type 2)

Primary outcomes

1

Description
Decrease of the serum glucose level

Timepoint
3 months

Method of measurement
Medical laboratory (kit)

2

Description
Decrease of the blood glycosylated hemoglobin level

Timepoint
3 months

Method of measurement
Medical laboratory (kit)

Secondary outcomes

1

Description
Increase of the serum creatinin level

Timepoint
3 months

Method of measurement
Medical laboratory (kit)

2

Description
Increase of the serum level of the liver enzyme SGOT

Timepoint
3 months

Method of measurement
Medical laboratory (kit)

3

Description
Increase of the srum level of the liver enzyme SGPT

Timepoint
3 months

Method of measurement
Medical laboratory (kit)

Intervention groups

1

Description
Nettle aerial parts extract at the dose of one 500 mg capsule every 8 hours in addition to the oral synthetic antidiabetic drugs for 3 months
Category
Treatment - Drugs

2

Description
one placebo capsule every 8 hours in addition to the oral synthetic antidiabetic drugs for 3 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kamkar Hospital
Full name of responsible person
Dr. Mahmood Parham
Street address
Dey 19 Street
City
Qom

2

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Dr. Mahmood Parham
Street address
Shahid Beheshti Boulevard
City
Qom

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Institute of Medicinal Plants affiliated with ACECR
Full name of responsible person
Dr. Rezazadeh
Street address
Institute of Medicinal Plants, Research Complex of ACECR, Kavosh Boulevard, Supa Boulevard, Poleh Kordan, 55th kilometer of Tehran-Gazvin Freeway
City
Karaj
Grant name
28538
Grant code / Reference number
1447-33
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Institute of Medicinal Plants affiliated with ACECR
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

2

Sponsor
Name of organization / entity
Qom University of Medical Sciences
Full name of responsible person
Dr. Akram Heidari
Street address
Department of Community Medicine, Faculty of Medicine, Golestan Alley, Number 2 Alley, Moallem Jonubi Avenue
City
Qom
Grant name
34
Grant code / Reference number
15099
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qom University of Medical Sciences
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Institute of Medicinal Plants affiliated with ACECR
Full name of responsible person
Dr. Saeed Kianbakht
Position
Ph.D. in pharmacology, assistant professor of the Department of Pharmacology and Applied Medicine in
Other areas of specialty/work
Street address
Institute of Medicinal Plants, Research Complex of ACECR, Kavosh Boulevard, Supa Boulevard, Poleh

Kordan, 55th kilometer of Tehran-Gazvin Freeway
City
Karaj
Postal code
31979
Phone
+98 26147640109
Fax
+98 26 1476 4021
Email
kianbakht@imp.ac.ir; skianbakht@gmail.com; skianbakht@hotmail.com
Web page address
www.imp.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Faculty of Medicine of Qom University of Medical Sciences
Full name of responsible person
Dr. Akram Heidari
Position
Specialist in community medicine
Other areas of specialty/work
Street address
Department of Community Medicine, Faculty of Medicine, Golestan Alley, Number 2 Alley, Moallem Jonubi Avenue
City
Qom
Postal code
3713645612
Phone
+98 25178313701
Fax
+98 25 1773 7923
Email
heidari6@yahoo.com; heidari6@muq.ac.ir
Web page address
www.muq.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Full name of responsible person
Dr. Saeed Kianbakht
Position
Other areas of specialty/work
Street address
City
Postal code
Phone
Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty