

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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

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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 serum 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

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Institute of Medicinal Plants, Research Complex of ACECR, Kavosh Boulevard, Supa Boulevard, Poleh

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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

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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

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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