

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Study of the effect of hydroalcoholic extract of nettle (*Urtica dioica* L.) and aerobic exercise on oxidative stress in type 2 diabetic patients

Protocol summary

Summary

The purpose of this study is to evaluate the effect of hydro alcoholic extract of nettle and aerobic exercise on oxidative stress in patients with type 2 diabetes mellitus in a randomized double-blinded clinical trial design. 72 patients covered by Shahroud Diabetes Society according to inclusion criteria such as patient over the age 50 years old and common diabetes drugs usage and exclusion criteria such as patients with renal, liver diseases or non-compliance with treatment will randomly divide into three groups, control group: patients with type 2 diabetes (24 women) which will not undergo any treatment, intervention group: patients with type 2 diabetes (24 women) that ingest 5cc of hydro alcoholic nettle extract and intervention group with aerobic exercise: patients with type 2 diabetes with aerobic exercise (24 participants) that ingest 5cc of hydro alcoholic nettle extract during 8 weeks. After and before 8 weeks of continuous treatment, blood sample will collect from patients to measure oxidative stress.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015031021412N1**

Registration date: **2015-04-11, 1394/01/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-04-11, 1394/01/22

Registrant information

Name

Hamid Kalalian Moghadam

Name of organization / entity

Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

h.kalalian@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahroud University of Medical Sciences

Expected recruitment start date

2014-02-18, 1392/11/29

Expected recruitment end date

2014-05-05, 1393/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of hydroalcoholic extract of nettle (*Urtica dioica* L.) and aerobic exercise on oxidative stress in type 2 diabetic patients

Public title

Effect of nettle extract and exercise in type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: female gender over the age of 50 years old; HbA1c levels equal or less than 10%; common diabetes drugs usage (Metformin and Glibenclamide); patients with triglyceride levels less than 400 mg dL-1. Exclusion criteria: patients with cardiovascular; renal; liver; thyroid diseases; infections; allergies; angina; the regular use of NSAIDs (Non-Steroid Anti Inflammatory

Drugs); warfarin; alcohol; herbal tea; dietary supplements; insulin injection.

Age

From **50 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee and Human Studies review board of Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences, Haftom Tir Square

City

Shahroud

Postal code

Approval date

2014-02-05, 1392/11/16

Ethics committee reference number

920/11

Health conditions studied

1

Description of health condition studied

Diabetes mellitus type 2

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

FPG

Timepoint

After and before 8 weeks of continuous treatment

Method of measurement

Blood test

2

Description

TG

Timepoint

After and before 8 weeks of continuous treatment

Method of measurement

Blood test

3

Description

SOD

Timepoint

After and before 8 weeks of continuous treatment

Method of measurement

Blood test

4

Description

NO

Timepoint

After and before 8 weeks of continuous treatment

Method of measurement

Blood test

5

Description

SGPT

Timepoint

After and before 8 weeks of continuous treatment

Method of measurement

Blood test

6

Description

SGOT

Timepoint

After and before 8 weeks of continuous treatment

Method of measurement

Blood test

7

Description

HDL

Timepoint

After and before 8 weeks of continuous treatment

Method of measurement

Blood test

8

Description

LDL

Timepoint

After and before 8 weeks of continuous treatment

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Control group: patients with type 2 diabetes (24 women) which will not undergo any treatment.

Category

N/A

2

Description

Intervention group patients with type 2 diabetes during 8 weeks will receive 5cc of hydro alcoholic nettle extract in 3 portions a day.

Category

Treatment - Drugs

3

Description

Intervention group with aerobic exercise during 8 weeks will receive 5cc of hydro alcoholic nettle extract in 3 portions a day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Hamid Kalalian Moghadam

Street address

Shahroud University of Medical Sciences, Haftom Tir Square

City

Shahroud

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Hamid Kalalian Moghadam

Street address

Shahroud University of Medical Sciences, Haftom Tir Square

City

Shahroud

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud University of Medical Sciences

Proportion provided by this source

100

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

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Hamid Kalalian Moghadam

Position

Assistant Professor of Physiology, Shahroud University of Medical Sciences

Other areas of specialty/work

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Position

Assistant Professor of Physiology, Shahroud University
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Other areas of specialty/work**Street address**

Shahroud University of Medical Sciences, Haftom Tir

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