# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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**
**Street address**
Shahroud University of Medical Sciences, Haftom Tir Square
**City**
Shahroud
**Postal code**
**Phone**
+98 23 3239 5054
**Fax**
**Email**
h.kalalian@shmu.ac.ir
**Web page address**

## Person responsible for scientific 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**
**Street address**
Shahroud University of Medical Sciences, Haftom Tir Square
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Shahroud
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**Email**
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**Web page address**

## Person responsible for updating data

**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**
**Street address**
Shahroud University of Medical Sciences, Haftom Tir Square
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## 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*