Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

The effect of 8 weeks of combined exercises and consumption of nettle extract on some renal indicators, lipid profile, insulin resistance in people with high blood pressure and type 2 diabetes

Protocol summary

Study aim
Determining the effect of 8 weeks of combined exercises and consumption of nettle extract on some renal indicators, lipid profile, insulin resistance in people with high blood pressure and type 2 diabetes.

Design
Clinical trial with control group, with parallel groups, randomized, on 40 patients. Randomization by the method of equal blocks (10 blocks of 4) in which a number of intervention people and a number of comparison people are included in each block.

Settings and conduct
By referring to the clinic and health network of Yangi Imam town located in Alborz province, eligible people were identified and placed in the intervention groups using equal blocks randomization (10 blocks of 4). Then, people will go to the sports club for training intervention and perform exercises and supplements for 8 weeks. And before and 24 hours after exercise interventions, blood samples are taken from people to be measured in the laboratory.

Participants/Inclusion and exclusion criteria
Entry requirements: type 2 diabetes Conditions of non-entry: inability to practice

Intervention groups
Group of combined and complementary exercises: in the group of combined exercises, the samples perform aerobic and resistance exercises, and the supplementary groups also consume nettle extract. The control group is not subjected to any intervention.

Main outcome variables
High blood pressure, lipid profile (triglycerides, cholesterol, etc.) and insulin resistance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221120056548N4**
Registration date: **2023-02-27, 1401/12/08**
Registration timing: **prospective**

Last update: **2023-02-27, 1401/12/08**
Update count: **0**

Registration date
2023-02-27, 1401/12/08

Registrant information

Name
Saeid Shamlou kazemi

Name of organization / entity
Bu-Ali Sina university

Country
Iran (Islamic Republic of)

Phone
+98 912 859 7297

Email address
saeidshamlou9092@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-28, 1401/12/09

Expected recruitment end date
2023-03-10, 1401/12/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of 8 weeks of combined exercises and consumption of nettle extract on some renal indicators, lipid profile, insulin resistance in people with high blood pressure and type 2 diabetes

Public title
The effect of exercise and nettle extract on type 2 diabetes
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Suffering from type 2 diabetes
Exclusion criteria:
History of cardiovascular disease
Age
From **45 years** old to **65 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this randomization, the method of equal blocks (10 blocks of 4) was used, in which a number of intervention people and a number of comparison people are included in each block, and we assigned them to different groups. The method and tool of block random sequence generation has been done using https://www.sealedenvelope.com/simple-randomiser/v1/lists.
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 of Sport Sciences Research Institute
Street address
Fifth Alley, Mir Emad Ave., Ostad Motahari Ave
City
Tehran
Province
Tehran
Postal code
1474674646
Approval date
2022-06-27, 1401/04/06
Ethics committee reference number
IR.SSRI.REC.1401.1576

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
E08
ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
The percentage of people whose blood pressure decreased.
Timepoint
Measurement before and after the intervention
Method of measurement
Using a mercury pressure gauge (ALPK2) made in Japan

2

Description
The percentage of people whose cholesterol, low-density lipoprotein and triglyceride levels have decreased.
Timepoint
Measurement before and after the intervention
Method of measurement
By testing blood samples

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: In the group of combined exercises (resistance-aerobic), training was about 180-190 minutes per week, 30 minutes of aerobic training and 30-40 minutes of resistance training in 3 sessions per week. In the initial sessions, after a 10-minute warm-up program, the participants walk on a treadmill for 20 minutes with an intensity of 60-70% of the maximum heart rate. In order to determine the intensity of the exercise, the maximum heart rate is calculated using the age-220 formula. After aerobic training, 5 minutes rest and then resistance training is done. In the first session, the resistance training is for

getting to know and learning the correct movements, the subjects do the first week with minimal weight and a few repetitions below the maximum. From the second week onwards, after estimating the one repetition maximum (1RM). Resistance training is performed with an intensity equivalent to 60 percent of a maximum repetition with 10 repetitions per movement for 3 consecutive sets of 30 seconds rest between each station and 120 seconds rest between each round. These exercises are programmed in 10 circular movements. Stations include: chest press, shoulder press (military), underarm lat, leg press, front thigh, lying back thigh, leg pull, front arm and back arm pull-up and sit-up. It is deadlift and squat. 5 minutes are allocated for cooling down. In order to comply with the principle of overload and increase the intensity, once every 2 weeks, a maximum repetition is re-measured and 60% of it is calculated. The intervention of extract consumption in supplement and exercise + supplement groups is carried out 15 minutes before the three main meals of breakfast, lunch and dinner and daily for eight weeks. According to previous studies, the dose of nettle was considered to be 10 grams per day, and 10 grams will be divided into three parts and consumed as an extract. Nettle extract will be prepared from the essential plant pharmaceutical company.

Category

Treatment - Other

2

Description

Control group: They are not subject to any intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Yangi Imam clinic and health network

Full name of responsible person

Saeid Shamlou Kazemi

Street address

Yengi Imam town

City

Karaj

Province

Alborz

Postal code

3149915968

Phone

+98 81 3221 0929

Email

saeidshamlou9092@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Danesh Alborz University

Full name of responsible person

Saeid Shamlou Kazemi

Street address

Bu-Ali Sina University, Shahid Mostafa Ahmadi Roshan Street, Hamedan

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3221 0929

Email

saeidshamlou9092@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Danesh Alborz University

Proportion provided by this source

10

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Bu-Ali Sina University

Full name of responsible person

Saeid Shamlou Kazemi

Position

Student

Latest degree

Master

Other areas of specialty/work

Sport Medicine

Street address

Mahdiyeh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3221 0929

Email

saeidshamlou9092@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bu-Ali Sina University

Full name of responsible person
Saeid Shamlou Kazemi

Position
Student

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saeidshamlou9092@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Bu-Ali Sina University

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
It will be available for researchers working in academic and scientific institutions.

Under which criteria data/document could be used
If the intellectual rights are preserved, the data can be sent to the researchers.

From where data/document is obtainable
Email address: saeidshamlou9092@gmail.com

What processes are involved for a request to access data/document
Submission of a written request (one week)

Comments