

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of 8 weeks Resistance Band training with Nigella sativa seed supplementation on the Levels of antioxidant enzymes in overweight women

Protocol summary

Study aim

Considering the anti-oxidant activity of Nigella Sativa by advising healthy people in order to reinforce antioxidant defending system can prevent disease (initial prevention) and in the patients also by reinforcing this system prevent the complications of disease or delay their appearance. With increasing the intensity of physical activity the oxidative stress, Lipid peroxidation and insufficiency of antioxidant defending system appears.

Design

Clinical trial having control group, has been randomized based on the community and pragmatic with parallel, two-way blind.

Settings and conduct

initially, the first blood sampling and after two months after the last exercise session and using tablet the last step blood sampling is performed. The assignment sequence is hidden by the envelopes encoded in the order numbered, and the letter envelopes are opened only after the end of all initial and basic evaluations related to the participants.

Participants/Inclusion and exclusion criteria

statistical population of the study include 300 individuals with over weight by age range of 20 to 40 years old that are active in the gyms of Mashahad city. They are divided after matching based on the body mass index ($25 < \text{BMI} < 30$).

Intervention groups

Before the start of exercise program and use of supplement, during a briefing session, the specifications and history of disease of individuals are gathered by questionnaire of general health and their medical background. All volunteers will participate in a training program concerning the correct way of performing the exercises and how to use the supplement. Another objective of the course is training the reduction of

subjects number through getting familiar with the exercise capacity of volunteers that may due to limitation/physical pain aren't able to complete the exercise plan.

Main outcome variables

anti oxidant levels, obesity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180612040080N1**

Registration date: **2018-09-22, 1397/06/31**

Registration timing: **retrospective**

Last update: **2018-09-22, 1397/06/31**

Update count: **0**

Registration date

2018-09-22, 1397/06/31

Registrant information

Name

malihe asiaban siuki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3272 1415

Email address

malihe_asiaban@shahroodut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-01, 1397/04/10

Expected recruitment end date

2018-09-01, 1397/06/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
Effect of 8 weeks Resistance Band training with Nigella sativa seed supplementation on the Levels of antioxidant enzymes in overweight women
Public title
The effect of exercise and black seed on the levels of antioxidant enzymes
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
BMI between 25 and 30
Exclusion criteria:
Menopause Weight Loss
Age
From **20 years** old to **40 years** old
Gender
Female
Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
To allocate participants to research groups, a computational list of random numbers using a computer software (Random Allocation Software 2.0) is initially created by one of the research colleagues. Then, the allocation of participants according to the body mass index varied in 4 groups using randomized block method. The limitation of this method is the prediction of final allocation, which is the solution of random use of blocks of different sizes. Assignment sequences are hidden by the envelopes encoded in the order numbered, and the letter envelopes are opened only after all the initial and initial evaluations of the participants have been made.
Blinding (investigator's opinion)
Double blinded
Blinding description
Combination of the main black granular supplement with placebo
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name

دانشگاه علوم پزشکی شاهرود

Secondary trial Id

IR.SHMU.REC.1397.039

Registration date

2018-05-23, 1397/03/02

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrood Medical Sciences

Street address

Shahrood University of Medical Sciences

City

shahrood

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۷

Approval date

2018-05-23, 1397/03/02

Ethics committee reference number

IR.SHMU.REC.1397.039

Health conditions studied

1

Description of health condition studied

Overweight

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

antioxidants level

Timepoint

Initial blood collection and then the final blood sampling, after two hours after 48 hours after the last training session or supplementation.

Method of measurement

Measurements are made by the glutathione peroxidase and superoxide dismutase kits of America.

Secondary outcomes

empty

Intervention groups

1

Description

Control group: The control group had their daily activities and did not attend sports exercises and did not use any supplement. They are asked to stay in their diet until the end of the intervention period and not to change it.

Category

Placebo

2

Description

Intervention group 1: A daily black currant supplement group will take one 1000 mg capsule at a time, 30 minutes before meals.

Category

Treatment - Drugs

3

Description

Intervention group 2: Practice protocol 6 sessions per week for 8 weeks and each session for one hour (10 minutes of warming up 40 minutes, doing special exercises and 10 minutes of cooling) to practice, and after 8 weeks of post-test training.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Exercise gym in Mashhad

Full name of responsible person

Malihe Asiaban Siuki

Street address

No.1155, Between Tabarsi 55 and 57 Ave, Exercise gym

City

Mashhad

Province

Razavi Khorasan

Postal code

91489-16313

Phone

+98 51 3272 1415

Email

malihe_asiaabn@shahroodut.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Shahrood

Full name of responsible person

Ali Hassani

Street address

University campus, Shahrood University

City

Shahrood

Province

Semnan

Postal code

3619995161

Phone

+98 23 3239 2204

Email

hassani_3@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

The University of Shahrood

Proportion provided by this source

100

Public or private sector

Public

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

The University of Shahrood

Full name of responsible person

Malihe Asiaban Siuki

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Public Health

Street address

No.11, Meghdad 16., Gaz sharghi Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9148916313

Phone

+98 51 3272 1415

Email

malihe_asiaban@shahroodut.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

The University of Shahrood

Full name of responsible person

Malihe Asiaban Siuki

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Public Health

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

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

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

The University of Shahrood

Full name of responsible person

Malihe Asiaban Siuki

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Public Health

Street address