Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effects of 8 Weeks of Resistance Training with Creatine Monohydrate Supplementation on Oxidative Stress and Antioxidant Indices in Older Adults

Protocol summary

Study aim

The aim of this study is investigate the effects of an 8-week endurance training along with the consumption of creatine monohydrate on serum levels of 8-hydroxy-2'-deoxyguanosine (8-OHDG), Malondialdehyde (MDA), Glutathione peroxidase (GPX) and Total Antioxidant Capacity (TAC) among the elderly.

Design

The study is a randomized clinical trail with control group double blinded. Fourty five old men and women (55-70 years) will be selected through purposive sampling and will randomly be divided into three groups: resistance training + placebo, resistance training + creatine monohydrate and control groups.

Settings and conduct

The present study is experimental which will be done in the form of a pretest-posttest design with a control group. The place of research is in the gym. Three professional coaches will train the subjects and a lab technetium will take their blood samples. Blood sample will be analyzed in the lab. The subjects in experimental groups will not know in which group they are. For the placebo- resistance training as much as creatine supplement, Maltodextrin is used as placebo

Participants/Inclusion and exclusion criteria

Inclusion criterion: 55-70 year old people. Non-inclusion criteria: back pain, history of lumbar surgery, cardiovascular disease, taking a medicine which is effective on study outcomes, Metabolic sickness history, Clinical limitations for sports activities

Intervention groups

Intervention groups of resistance training + placebo and resistance training+creatine monohydrate supplement will do resistance training 3 sessions per week for 8 weeks. Control group will not participate in any exercise

Main outcome variables

8-hydroxy-2'-deoxyguanosine (8-OHDG), Malondialdehyde (MDA), Glutathione peroxidase (GPX), Total Antioxidant Capacity (TAC)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201121049453N1**
Registration date: **2021-01-27, 1399/11/08**
Registration timing: **prospective**

Last update: **2021-01-27, 1399/11/08**
Update count: **0**

Registration date

2021-01-27, 1399/11/08

Registrant information

Name

Ehsan Amiri

Name of organization / entity

The University of Kurdistan

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effects of 8 Weeks of Resistance Training with Creatine Monohydrate Supplementation on Oxidative Stress and Antioxidant Indices in Older Adults

Public title
The effect of Resistance Training with Creatine Monohydrate Supplementation on Oxidative Stress and Antioxidant Indices
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 55-70 years old
Exclusion criteria:
Back pain History of lumbar surgery Cardiovascular disease Metabolic sickness history Clinical limitations for sports activities
Age
From **55 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization: First each subject will be taken in each groups (A or B) by tossing a coin. Each side of the coin determines the assignment of each subject. Then each group will be named as control or experimental group by tossing a coin.
Blinding (investigator's opinion)
Double blinded
Blinding description
First, the subjects in the experimental group are randomly divided into two groups: resistance training + creatine monohydrate supplement and resistance training + placebo. The subjects will not know in which group they are. Creatine monohydrate and placebo were identical in amount, taste, texture, color, and appearance. The supplement packages were coded so that neither the investigators nor the participants were aware of the contents until completion of the analyses. The supplements were provided by a staff member of research team who did not have any participation in the data acquisition, analyses, and interpretation.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics commitee of Kurdistan University
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Pasdaran boulevard
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Approval date
2020-06-06, 1399/03/17
Ethics committee reference number
IR.UOK.REC.1399.010

Health conditions studied

1

Description of health condition studied
Resistance training
ICD-10 code
Y93.B
ICD-10 code description
Activities involving other muscle strengthening exercises

Primary outcomes

1

Description
Malondialdehyde (MDA)
Timepoint
Before and after 8 weeks resistance training
Method of measurement
By ELISA method

2

Description
Glutathione peroxidase (GPX)
Timepoint
Before and after 8 weeks resistance training
Method of measurement
By ELISA method

3

Description
Total antioxidant capacity (TAC)
Timepoint
Before and after 8 weeks resistance training
Method of measurement
By ELISA method

4

Description
8-hydroxy-2' -deoxyguanosine (8-OHdG)
Timepoint
Before and after 8 weeks resistance training
Method of measurement
By ELISA method

Secondary outcomes

1

Description
Muscle strength
Timepoint
Before and after 8 weeks resistance training
Method of measurement
One Repetition maximum

2

Description
Blood Creatinine
Timepoint
Before and after 8 weeks resistance training
Method of measurement
Blood sampling

3

Description
Quality of Life
Timepoint
Before and after 8 weeks resistance training
Method of measurement
Questionnaire (SF-36) Quality of Life

4

Description
Body mass index
Timepoint
Before and after 8 weeks resistance training
Method of measurement
weight(kg)/height(m2)

Intervention groups

1

Description
Intervention group 1: 15 participants as a resistance training + creatine monohydrate supplement group received 0.1g•kg/day of creatine (under license from Canada, Gene Star Company and approved by the Ministry of Health of Iran) every day for 8 weeks. subjects consumed the supplement as a single dose after training session (similar time in non training dayes). The supplement packages were coded so that neither the investigators nor the participants were aware of the contents until completion of the analyses. The supplements were provided by a staff member of research team who did not have any participation in the data acquisition, analyses, and interpretation. The training protocol will consist of 3 sets of 10 reps at 75% of 1RM. Resting time between sets and movements were performed for 2 and 3 minutes , respectively. Blood sampling will be performed 48 hours before the start of training and 48 hours after the last training session in the fasting state.
Category
Other

2

Description
Intervention group 2: 15 participants as a resistance training + placebo group did resistance training for 8 weeks. The training was consist of 3 sets of 10 reps at 75% of 1RM. Resting time between sets and movements were performed for 2 and 3 minutes , respectively. Creatine and placebo (Globe Plus 10 DE Maltodextrin, Univar Canada) were identical in amount, taste, texture, color, and appearance. Fasting blood sampling were taken 48 hours before the training and 48 hours after the last training session.
Category
Placebo

3

Description
Control group: 15 participant as control group were asked not to participate in any exercise program and keep on their regular diet during research and report any changes in their life like disease, serious stress
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
University of kurdistan
Full name of responsible person
Kyomars Karami
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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

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

Title of funding source
University of Kurdistan

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
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Ehsan Amiri

Position
student

Latest degree
Master

Other areas of specialty/work
exercise Physiology

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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is 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
When the data will become available and for how long
6 months after data publication
To whom data/document is available
Student and academic staff
Under which criteria data/document could be used
every analyses is fine for future research
From where data/document is obtainable
researcher
What processes are involved for a request to access data/document
By sending email to researcher
Comments