# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Jul 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
**Street address**
Pasdaran boulevard
**City**
Sanandaj
**Province**
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**Postal code**
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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**
University of Kurdistan

**Full name of responsible person**
Ehsan Amiri

**Position**
student

**Latest degree**
Master

**Other areas of specialty/work**
exercise Physiology

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## Person responsible for scientific inquiries

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Associate professor

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## Person responsible for updating data

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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**