

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of oral consumption of N-acetyl Cysteine in reducing the injuries caused by a single bout of exhaustive exercise in untrained young subjects

Protocol summary

Summary

The aim of the current study was to evaluate the effect of N-acetyl cysteine (NAC) supplementation on markers of oxidative stress and inflammatory response during a single bout of exhaustive exercise. Inclusion criteria were, participants aged between 21 and 25, either sex and exclusion criteria were, subjects who were consuming energetic drugs, smokers and those having any type of regular sport activity. In a randomized placebo-controlled double-blind clinical trial, thirty healthy, untrained young university students from both sex (males and females) with the age between 21 and 25 were selected and divided into 2 groups, including case (600 mg of effervescent tablets of N-acetyl Cysteine) and the control group(placebo Neutral cellulose) .Starting 24 hours before the supplementation ,blood samples were taken from all the subjects. The next blood samples were collected just before the exercise started, immediately after the exhaustive exercise (on flat treadmill running) and after one hour at rest. Malondialdehyde (MDA), total antioxidative capacity (TAC), CRP, BMI and Vo2 max were determined. We hypothesize that consumption of oral N-acetyl Cysteine before an exhaustive exercise reduces the parameters of oxidation stress and inflammation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208238129N2**

Registration date: **2013-05-10, 1392/02/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-05-10, 1392/02/20

Registrant information

Name

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

provided by the main researcher, with the help of deputy of research, Bushehr University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-05-31, 1392/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral consumption of N-acetyl Cysteine in reducing the injuries caused by a single bout of exhaustive exercise in untrained young subjects

Public title

Effect of N-acetyl cysteine in reducing the injuries caused by exhaustive exercise

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: participants aged between 21 and 25; either sex; having Vo2 max between 35 to 40 ml/kg/min ; and living in the same dormitory ; all having the same type of food. Exclusion criteria: subjects who were consuming energetic drugs; smokers; those having any type of regular sport activity.

Age

From **21 years** old to **25 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Deputy Adviser, Bushehr University of Medical Sciences

Street address

Bushehr University of Medical Sciences, Reshehr street, Next to Salmon farsi Hospital, Bahmani, Bushehr, Iran.

City

Bushehr

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987518759577

Approval date

2013-04-23, 1392/02/03

Ethics committee reference number

B-15-92-2

Health conditions studied

1

Description of health condition studied

oxidative stress injuries

ICD-10 code

ICD-10 code description

-

Primary outcomes

1

Description

Total antioxidant capacity

Timepoint

Before the consumption of drug; one hour before start of the exercise; Immediately after exercise; after one at rest hour

Method of measurement

By ELISA method and commercial kits

2

Description

C-reactive protein (CRP)

Timepoint

Before the consumption of drug; one hour before start of the exercise; Immediately after exercise; after one at rest hour

Method of measurement

By ELISA method and commercial kits

3

Description

Malonaldehyde

Timepoint

Before the consumption of drug; one hour before start of the exercise; Immediately after exercise; after one at rest hour

Method of measurement

By spectrophotometry

Secondary outcomes

1

Description

BMI

Timepoint

Before the trial

Method of measurement

weight in kilograms divided by the square of height in meters

2

Description

Vo2 max

Timepoint

Before and after the trial

Method of measurement

Cooper Standard Aerobic Test was used

Intervention groups

1

Description

Intervention group:effervescent tablets of N-acetyl cysteine as 4 times starting 24 hours before the trial

Category

Prevention

2

Description

placebo group: dextrose %3 as dissolved in water

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

The Persien Gulf Biomedical Research Institute

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research,Bushehr University of Medical Sciences

Full name of responsible person

Afshin Ostowar

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Bushehr University of Medical Sciences,Reshehr Street, Next to Salmon Farsi Hospital, Bahmani.

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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

Deputy of Research,Bushehr 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

Bushehr University of Medical Sciences

Full name of responsible person

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Position

Ph.D in Biochemistry, Academic member

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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