

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effects of ten weeks aerobic exercise accompanied by vitamin E supplement consumption on addicted women's blood pressure, Heart rate, and vo2max

Protocol summary

Summary

The major aim of the current study is to investigate the effects of 10 weeks aerobics exercise accompanied by vitamin E supplementation on blood pressure, heart rate, and VO2max consumption in addicted women. This study will be a phase 2 trial not blind with a pre-test and post-test. The population of this experimental study is addicted women in Zahedan Addiction Camp. Based on simplified random sampling 38 addicted women will be chosen and classified into four groups, exercise + placebo (n = 10), exercise + vitamin E (n=10), vitamin E (n=10) and placebo (n = 8) and will receive supplementation and placebo during 10 weeks. The experimental group will be studied for 10 weeks (three sessions per a week) 40 up to 50 minutes with 40 to 75 percent maximum heart rate. Before the training the main variables such as blood pressure, heart rate, maximal oxygen uptake, as well as secondary variables, body mass index and weight will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082223715N1**

Registration date: **2016-04-16, 1395/01/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-16, 1395/01/28

Registrant information

Name

Somaye Aram

Name of organization / entity

University of Sistan and Baluchestan, Zahedan

Country

Iran (Islamic Republic of)

Phone

+98 54 3350 4189

Email address

m_ghofrani2000@ped.usb.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-11-28, 1393/09/07

Expected recruitment end date

2015-02-09, 1393/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of ten weeks aerobic exercise accompanied by vitamin E supplement consumption on addicted women's blood pressure, Heart rate, and vo2max

Public title

Effects of aerobic exercise and supplementation with vitamin E in the treatment of addiction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all people in the Addiction Camp. those with diseases such as blood fat , blood sugar :blood pressure. Cancer Or any other disease :Exclusion criteria

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 38

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of zahedan University of Medical Sciences

Street address

Doctor Hesabi Field ,End of the University street

City

zahedan

Postal code

Approval date

2014-11-27, 1393/09/06

Ethics committee reference number

129-933/3/6017

Health conditions studied

1

Description of health condition studied

-

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Blood pressure

Timepoint

Before the intervention and at the end of 10 weeks

Method of measurement

Common Indicator

2

Description

Heart Reat

Timepoint

Before the intervention and at the end of 10 weeks

Method of measurement

Polar Rate monitor

3

Description

Maximum Oxygen uptake

Timepoint

Before the intervention and at the end of 10 weeks

Method of measurement

1600 miles march teast

Secondary outcomes

1

Description

Weight

Timepoint

Before the intervention and at the end of 10 weeks

Method of measurement

Digital Balance

2

Description

Body mass index

Timepoint

Before the intervention and at the end of 10 weeks

Method of measurement

Weight divided by the square of height

Intervention groups

1

Description

Intervention group1: Exercise + Placebo! Aerobic exercise , For 10 weeks, 3 Seance a week! Starch Placebo 0.4 gram, on befor lunch daily, for 10 weeks

Category

Other

2

Description

Intervention group2: Exercise + Vitamin E, Earobic exercise, For 10 weeks,3 Seance a week! Vitamin E : 400 doses, on before lunch daily, for 10 weeks.
Pharmaceutical company Dana

Category

Other

3

Description

Control group: Starch 0.4 gram, on before lunch daily, for 10 weeks

Category

Placebo

4

Description

Intervention group3: Vitamin E 400 doses, on before lunch daily , for 10 weeks, Dana pharmaceutical company

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

women quit addiction Camp

Full name of responsible person

Street address

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research University of Sistan and Baluchestan

Full name of responsible person

Kordi Tamandani Dor Mohammad Docter

Street address

Central Organization University of Sistan and Baluchestan

City

zahedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research University of Sistan and Baluchestan

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

University of Sistan and Baluchestan Zahedan

Full name of responsible person

Aram Somaye

Position

Student

Other areas of specialty/work

Street address

Saadi 67Alley , Saadi Westerly street, Zahedan

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Person responsible for scientific inquiries

Contact

Name of organization / entity

University of Sistan and BaluchestanZahedan

Full name of responsible person

Ghofrani Mohsen

Position

Sport Management. Ph.d

Other areas of specialty/work

Street address

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City

Zahedan

Postal code

Phone

+98 54 3343 1065

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Email

m_ghofrani2000@ped.usb.ac.ir

Web page address

Person responsible for updating data

Contact

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