

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The Effect of a Low-carbohydrate Diet Combined with CrossFit Training on Ghrelin levels, Insulin and Performance in Active Woman.

Protocol summary

Study aim

The aim of this study was to determine the effect of low carb diet and cross fit training on ghrelin, insulin and appetite levels

Design

A clinical trial including a control group with 80 participants with parallel groups, was randomized

Settings and conduct

After the initial assessments, 80 people were randomly selected as a sample in Isfahan. Then, written consent is obtained from the participants. The individuals were randomly divided into four groups. Blood samples are collected and analyzed before and after 12 weeks to measure serum ghrelin and insulin concentrations.

Participants/Inclusion and exclusion criteria

Age in the range of 25 to 40 years

Intervention groups

Intervention group 1: Low carb diet, low carb diet including 40% carbohydrates, 40% fat, and 20% protein Intervention. Group 2: Cross-fit training, training for eight weeks, and three sessions of cross-fit training per week, including weightlifting, gymnastics Intervention. Group 3: Combination (diet and exercise). Control group: without intervention.

Main outcome variables

Serum ghrelin concentration and serum insulin concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181224042106N1**

Registration date: **2021-06-16, 1400/03/26**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-16, 1400/03/26**

Update count: **0**

Registration date

2021-06-16, 1400/03/26

Registrant information

Name

Shokoofeh Samouei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3263 1253

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-10, 1400/03/20

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of a Low-carbohydrate Diet Combined with CrossFit Training on Ghrelin levels, Insulin and Performance in Active Woman.

Public title

A review of low-carbohydrate diet and crossfit on women's performance

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Have at least 6 months of functional training Normal BMI
Cardiovascular health Don't use hormones , stimulants
and fat burners drugs, During the study

Exclusion criteria:

Skeletal, muscular and metabolic problems that limiting
exercise activities Enter the menopausal period Have
blood pressure and diabetes

Age

From **25 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization;
Randomization Tool: Random Number Table;
Randomization Unit: Individual; For using a random
number table, the researcher determined the reading
position of the table numbers. Then the numbers were
considered for different groups. After that, the numbers
were recorded and assigned to four groups, including low
carbohydrate diet, cross-fit training, combination, and
control. Furthermore, to hide random allocation, the
method of coded boxes with the random sequence was
used. In this method, several boxes that are numbered
based on a random sequence were provided.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee on Research Islamic Azad
University - Isfahan Branch (Khorasgan)

Street address

University Blvd , Arghavanie , East Gay Street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8155139998

Approval date

2019-07-16, 1398/04/25

Ethics committee reference number

IR.IAU.KHUISF.REC.1398.138

Health conditions studied

1

Description of health condition studied

Female Athletes

ICD-10 code

Y93.B9

ICD-10 code description

Activity, other specified sports and athletics

Primary outcomes

1

Description

Serum ghrelin concentration

Timepoint

At the beginning and end of the study after 8 weeks

Method of measurement

Serum concentration of ghrelin by ELISA method using
the Lake.Inc Monobind USA.C kit in USA

2

Description

Serum insulin concentration

Timepoint

At the beginning and end of the study after 8 weeks

Method of measurement

Serum concentration of insulin by ELISA method using
the (Sweden, Uppsala, Mercodia) kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1:Low carb diet, low carb diet includes
40% carbohydrates, 40% fat and 20% protein

Category

Lifestyle

2

Description

Intervention group 2: Cross-fit training, training for 8
weeks and 3 sessions of cross-fit training per week,
including weightlifting, gymnastics

Category

Rehabilitation

3

Description

Intervention group 3: Low carb diet, low carb diet including 40% carbohydrates, 40% fat and 20% protein and cross-fit workout, workout for 8 weeks and 3 sessions of cross-fit workouts per week including weightlifting, gymnastics

Category

Lifestyle

4

Description

Control group: Control group: No intervention, only follow up

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Diet Therapy , Isfahan Clinic Hospital

Full name of responsible person

Hajar Bahador

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Isfahan Hospital ,Ordibehesht Ave SheikhBahaei St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University, Isfahan Branch (Khorasgan),
Research Deputy

Full name of responsible person

Majid Toghiani

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Khorasgan University, Arghavanie St, Isfahan

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Grant name

Grant code / Reference number

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

No

Title of funding source

Islamic Azad University, Isfahan Branch (Khorasgan),
Research Deputy

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

Islamic Azad University

Full name of responsible person

Farzaneh Taghian

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available