

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effects of gamma oryzanol supplementation on lipid profile, anabolic/catabolic hormones, circulating binding proteins and anthropometric changes in young males during resistance training

Protocol summary

Summary

The objective of this single blind, placebo-controlled, randomized intervention trial is to determine the effects of dietary 600 mg/day gamma oryzanol supplementation during a 9-week resistance training program on altering lipid profile, anabolic/catabolic hormones, circulating binding proteins and anthropometric measures of young males during resistance training. Thirty two (32) eligible males with no continuous resistance training experience during six months before the study participation, with age 18-24 years were selected for the study and were randomized into two groups (either 600 mg of gamma oryzanol or lactose in the form of capsules). Prior to the study commencement, subjects' squat 1 Repetition Maximum (1RM) was determined by means of 1RM strength tests on the regular leg curl and bench press machine, which was repeated on the last day of study. The main inclusion criteria were including having no previous continuous resistance training (as having resistance training for at least 20 minutes 2 to 3 times per week without stopping) during last 6 months before the study commencement; being males and age between 18-30. The main exclusion criteria consisted of: A history of cardiovascular disease; Lactose intolerance; Diabetes mellitus; Cancer; Hypertension; Chronic obstructive pulmonary disease; Psychiatric disease; Any other serious life-threatening illness that required regular medical treatment; Alcohol intake of 15 drinks or more per week or at least 30 g/d; <4d/week of recommended resistance exercise; <80% of provided supplement or placebo capsules; Smokers, or tobacco product consumers; Taking any weight loss drug or participating in any weight loss program or changing their diets for example vegetarian diet; Anti-inflammatory drugs, hormones supplements or any other supplements before (for a minimum of six months) or during the study period; Concurrent participation in other physical or

exercise modalities. The intervention under study was supervised resistance training was performed four times a week, performing three sets (consisting of 6-12 repetitions) per exercise with three minutes rest, for a period of 9 weeks for each participant, accompanied with the consumption of supplement or placebo. At the study commencement in two times, before and after the acute resistance exercise, and at the end of the 9-week and 24 hours after the last resistance exercise performance, blood sampling were taken following 10-12 hour fast. Also, anthropomorphic measurements and physical performance were obtained before and after accomplishment of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013120715694N1**

Registration date: **2014-05-05, 1393/02/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-05, 1393/02/15

Registrant information

Name

Saghar Eslami

Name of organization / entity

UNSW

Country

Australia

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Recruitment status**Recruitment complete****Funding source**

Vice chancellor for research, University of Putra Malaysia

Expected recruitment start date

2010-02-10, 1388/11/21

Expected recruitment end date

2010-04-17, 1389/01/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of gamma oryzanol supplementation on lipid profile, anabolic/catabolic hormones, circulating binding proteins and anthropometric changes in young males during resistance training

Public title

Gamma oryzanol Supplementation Study

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: having no previous continuous resistance training (having resistance training for at least 20 minutes 2 to 3 times per week without stopping) during last 6 months before the study commencement; being males and age between 18-30; Exclusion criteria: A history of cardiovascular disease; Lactose intolerance, Diabetes mellitus, Cancer, Hypertension, Chronic obstructive pulmonary disease, Psychiatric disease; Any other serious life-threatening illness that required regular medical treatment; Alcohol intake of 15 drinks or more per week or at least 30 g/d <4d/week of recommended resistance exercise; <80% of provided supplement or placebo capsules; Smokers, or tobacco product consumers; Taking any weight loss drug or participating in any weight loss program or changing their diets for example vegetarian diet; Anti-inflammatory drugs, hormones supplements or any other supplements before (for a minimum of six months) or during the study period; Concurrent participation in other physical or exercise modalities

AgeFrom **18 years** old to **30 years** old**Gender**

Male

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **32****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Medical research ethic committee , University of Putra Malaysia

Street address

Faculty of Medical Science

City

selangor

Postal code**Approval date**

2010-01-12, 1388/10/22

Ethics committee reference number

UPM/FPSK/T7-MJKEthicaPer/F01(JPD-OKT(09)68)

Health conditions studied**1****Description of health condition studied**

improving Anabolic and catabolic hormones alterations and blood lipid profile as well improving anthropometric measurements following resistance exercise in young males

ICD-10 code

Z10

ICD-10 code description

Routine general health check-up of defined subpopulation

Primary outcomes**1****Description**

lipid profile

Timepoint

9 weeks

Method of measurement

blood analysis

2**Description**

Anabolic and catabolic hormones

Timepoint

9 weeks

Method of measurement

blood analysis

Secondary outcomes

1

Description

Anthropometric changes

Timepoint

9 weeks

Method of measurement

Anthropocentric measurements

Intervention groups

1

Description

Supplement group: After first blood sampling, all the subjects performed acute heavy resistance protocol (AHRE) consisting of 6 sets of 10 repetitions with 80% 1RM, followed by second blood sampling. Each subjects consumed 600mg gamma oryzanol as supplement group for 9 weeks.

Category

N/A

2

Description

Placebo group: After first blood sampling, all the subjects performed acute heavy resistance protocol (AHRE) consisting of 6 sets of 10 repetitions with 80% 1RM, followed by second blood sampling. Each subjects consumed 600mg lactose as placebo (control) group for 9 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Sport Sciences, University of Isfahan

Full name of responsible person

Saghar Eslami

Street address

Faculty of Sport Sciences, University of Isfahan,
Hezar-Jerib Ave,

City

Isfahan,

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, University of Putra

Malaysia

Full name of responsible person

Associate Professor Norhaizan Mohd. Esa

Street address

Faculty of Medicine and Health Sciences, University of
Putra Malaysia, Jalan Jasmin,

City

Serdang,

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 Putra Malaysia

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 Putra Malaysia

Full name of responsible person

Saghar Eslami

Position

PhD

Other areas of specialty/work

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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

Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Street address