

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of changes in lymphocyte subpopulations during weight loss program on obese subjects and control group

Protocol summary

Summary

Objective: To study the effect of weight loss program on plasma count of important lymphocyte subtypes (CD3, CD4, CD8, CD19, CD16/56) in non-pregnant, non-lactating, obese premenopausal females and comparison to the control group. Methods: In a randomized controlled trial, 29 females were enrolled. The intervention group was selected by chance, and the control group was matched by BMI and age with cases. All the intervention and control subjects must be analyzed for their healthy status. Blood sampling for primary outcome measures was done in one of these days of cycle (7th, 8th, 9th, 10th of monthly cycle). Body composition, serum zinc and iron status and plasma count of lymphocyte subpopulations were measured, at baseline and at the end of the intervention. Intervention group received a low calorie diet (3976.7 kJ/ 950 kcal per day) plus Lipase inhibitor (Orlistat), soluble fiber, and daily moderate physical activity (VO₂max 60%), until 10-15% weight loss. Data were analyzed and compared between intervention and control groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052617872N1**

Registration date: **2014-10-30, 1393/08/08**

Registration timing: **na**

Last update:

Update count: **0**

Registration date

2014-10-30, 1393/08/08

Registrant information

Name

Mahsa Mehrdad

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Not enough for processing

Funding source

Vice Chancellor for Research of Mashhad University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of changes in lymphocyte subpopulations during weight loss program on obese subjects and control group

Public title

assessment of immune system during Low Calorie Diet induced weight loss

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: Female; Age 25-40years; BMI \geq 30.00; Normal thyroid function; Normal blood cortisol; Normal menstruation; Healthy individuals(without any certain diseases); Normal HbA1c; Normal blood glucose test; Non smokers; non alcohol consumption Exclusion

criteria:Any drug consumption; Anemic Individuals

Age

From **25 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **29**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Mashhad University of Medical Sciences

Street address

Medicine Faculty, Mashhad University of Medical Sciences, Vakil Abad Avenue, Mashhad, Khorasan Razavi

City

Mashhad

Postal code

Approval date

2012-05-23, 1391/03/03

Ethics committee reference number

900413

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66.9

ICD-10 code description

Simple obesity NOS

Primary outcomes

1

Description

T Lymphocyte CD4+

Timepoint

Before and after the intervention (Day 0 of intervention and after 10-15% weight loss)

Method of measurement

flow cytometry

2

Description

T Lymphocyte CD3+

Timepoint

Before and after the intervention (Day 0 of intervention and after 10-15% weight loss)

Method of measurement

flow cytometry

3

Description

B Lymphocyte CD19+

Timepoint

Before and after the intervention (Day 0 of intervention and after 10-15% weight loss)

Method of measurement

flow cytometry

4

Description

Natural Killer Cells CD16/56+

Timepoint

Before and after the intervention (Day 0 of intervention and after 10-15% weight loss)

Method of measurement

flow cytometry

5

Description

T Lymphocyte CD8+

Timepoint

Before and after the intervention (Day 0 of intervention and after 10-15% weight loss)

Method of measurement

flow cytometry

Secondary outcomes

1

Description

Zinc

Timepoint

Before and after the intervention (Day 0 of intervention and after 10-15% weight loss)

Method of measurement

Blood test

2

Description

Iron

Timepoint

Before and after the intervention (Day 0 of intervention and after 10-15% weight loss)

Method of measurement

Blood test

Intervention groups

1

Description

Low Calorie Diet by 500 Kcal less than requirement up to 10-15% weight loss

Category

Treatment - Other

2

Description

administration of orlistat(120mg) twice a day with lunch and dinner

Category

Treatment - Drugs

3

Description

1 hour moderate physical activity(VO2 max 60%)

Category

Lifestyle

4

Description

Administration of 15gr soluble fiber twice a day before lunch and dinner

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Qaem nutrition and diet therapy Clinic

Full name of responsible person

Dr.Abdolreza Norouzy

Street address

Qaem Clinic, Qaem Hospital, Ahmad Abad St, Mashhad, Khorasane Razavi

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Abdolreza Norouzy

Street address

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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

Mashhad 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

Mashhad University of Medical Sciences

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student

Other areas of specialty/work

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Web page address**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****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mahsa Mehrdad

Position

Ph.D student

Other areas of specialty/work**Street address**