Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Name of organization / entity

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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 ≥ 30.00; Normal thyroid function; Normal blood cortisol; Normal mensturation; 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 Scienses

Street address

Medicine Faculty, Mashhad University of Medical Scienses, 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

Befor 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

Befor 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

Befor 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

Befor 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

Befor 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

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

Method of measurement

Blood test

2

Description
Iron
Timepoint
Befor 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 reqirement 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 thrapy Clinic
Full name of responsible person
Dr.Abdolreza Norouzy
Street address
Qaem Clinic, Qaem Hospital, Ahmad Abad St, Mashhad, Khorasane Razavi
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Sponsors / Funding sources

1

Sponsor
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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 Scienses
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

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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