

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of second and third generation of compound oral contraceptives on lipid and carbohydrate metabolism in overweight and obese women: a randomized clinical controlled trial

Protocol summary

Summary

The aim of this randomized controlled trial (double blind) is comparing the effect of second and third generation of combined oral contraceptives on lipid and carbohydrate metabolism in overweight and obese women. In this study, 46 obese women and 91 overweight women aged 18 to 40 years old who are the applicants for combined oral contraceptives will be recruited. This study will be conducted at selected health care centers in Tabriz city. Eligible women will be selected through convenience sampling and will be randomly assigned into 2 groups using permuted block randomization with allocation ratio of 1:1. Random allocation sequence will be determined using a computerized program. Opaque sealed sequentially numbered envelopes from number 1 to 47 for obese women and from number 47 to 137 for overweight women will be used for allocation concealment. Intervention group will receive one Morolin tablet daily for first 21 days of each cycle and control group will receive one LD tablet daily for first 21 days of each cycle through three cycles. Main outcomes include serum levels of fasting blood glucose, total cholesterol, low density lipoprotein, high density lipoprotein after 12 hours fast and secondary outcomes include serum levels of blood glucose after 2-hour 75 gram oral glucose tolerance test and triglycerides after 12 hours fast that will be assessed by Spectrophotometric technique before the intervention and three months after intervention. The researcher and the participants will be blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402266709N15**

Registration date: **2014-06-14, 1393/03/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-14, 1393/03/24

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Research deputy of Tabriz University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of second and third generation of compound oral contraceptives on lipid and carbohydrate metabolism in overweight and obese women: a randomized clinical controlled trial

Public title

The effect of compound oral contraceptives tablets on lipid and carbohydrate metabolism in overweight and obese women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: married women; having regular, spontaneous menstrual cycles varying from 21 to 35 days; body mass index between 25 and 34.9 kilograms per square meter; fasting blood glucose lower than 126 milligrams per deciliter; blood glucose after 2-hour glucose tolerance test lower than 200 milligrams per deciliter; low density lipoprotein lower than 160 milligrams per deciliter; triglycerides lower than 250 milligrams per deciliter; having a desire to participate in the study Exclusion criteria: having absolute and relative contraindications of combined oral contraceptives; using hormonal contraceptive methods during the last 3 months; taking lipid lowering drugs such as lovastatin, Gemfibrozil, Atorvastatin, Cholestyramine, etc; having thyroid and renal diseases

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **137**

Randomization (investigator's opinion)

Randomized

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

Double 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 of Tabriz university of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Goltasht Street, Azadi Avenue, Tabriz

City

Tabriz

Postal code

51665118

Approval date

2014-04-28, 1393/02/08

Ethics committee reference number

9317

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

Effect of oral contraception tablets on metabolism

ICD-10 code

Z30.4

ICD-10 code description

Surveillance of contraceptive drugs

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

Fasting blood glucose

Timepoint

Before the intervention and three months after intervention

Method of measurement

Spectrophotometric technique

2**Description**

Total cholesterol

Timepoint

Before the intervention and three months after intervention

Method of measurement

Spectrophotometric technique

3**Description**

Low density lipoprotein

Timepoint

Before the intervention and three months after intervention

Method of measurement

Spectrophotometric technique

4**Description**

High density lipoprotein

Timepoint

Before the intervention and three months after intervention

Method of measurement

Spectrophotometric technique

Secondary outcomes

1

Description

Blood glucose after 2-hour 75 gram oral glucose tolerance test

Timepoint

Before the intervention and three months after intervention

Method of measurement

Spectrophotometric technique

2

Description

Triglycerides

Timepoint

Before the intervention and three months after intervention

Method of measurement

Spectrophotometric technique

Intervention groups

1

Description

Intervention group: tablet of contraceptive DE with trade name of Marolin made by Aburaihan Pharmaceutical Company in Tehran, containing 30 micrograms Ethinyl Estradiol and 150 micrograms Desogestrel, one pill daily for first 21 days of each cycle through three cycles

Category

Prevention

2

Description

Control group: tablet of contraceptive LD with trade name of Ovocept LD made by Aburaihan Pharmaceutical Company in Tehran, containing 30 micrograms Ethinyl Estradiol and 150 micrograms Levonorgestrel, one oral pill daily for first 21 days of each cycle through three cycles

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Public health centers of Tabriz city

Full name of responsible person

Dr Mitra Yeghaneh

Street address

Tabriz Health Centre, Jihad square, Nesf-e-rah Street, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy of Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohammadreza Rashidi

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City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research deputy of Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

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Position

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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