Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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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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, Golgasht 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, Jahad 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
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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