

# 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

###### Name

Mahnaz Shahnazi

###### Name of organization / entity

Tabriz University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1479 6770

###### Email address

mshahnazi@tbzmed.ac.ir

##### 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

##### City

Tabriz

## 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

##### Street address

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

##### 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

Samira Pourzeinali Beilankoo

##### Position

Master of sciences student in midwifery

##### Other areas of specialty/work

##### Street address

Faculty of Nursing and Midwifery, South Shariati Street, Tabriz

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5177854616

##### Phone

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##### Web page address

<http://nursing.tbzmed.ac.ir/>

## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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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*