

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Effects of Tibolone on cardiovascular disease in menopausal women

#### Protocol summary

##### Summary

As a frequently used hormone-like alternative to traditional HRT, it is valuable to compare the influence of Tibolone and HRT on cardiovascular diseases. A total of 156 healthy non-surgical postmenopausal women were included in an open labeled randomized study. 52 women received 2.5 mg Tibolone plus one Cal+D tablet (500 mg calcium and 200 IU vitamin D) daily, 52 women received 0.625 mg conjugated equine estrogen and 2.5 mg medroxy progesterone (CEE/MPA) plus one Cal+D tablet daily, and 52 women received only one Cal+D tablet as controls. The women were followed- up for six months. The body mass index (BMI), blood pressure(BP), serum lipids (HDL,LDL,TG), C reactive protein(CRP), sex hormone binding globulin (SHBG), free testosterone index (FTI), and free estradiol index (FEI) were determined before and after the interventions.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138901293743N1**

Registration date: **2010-06-04, 1389/03/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-06-04, 1389/03/14

##### Registrant information

###### Name

Saeideh Ziaei

###### Name of organization / entity

Tarbiat Modares University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8288 3555

##### Email address

ziaei\_sa@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tarbiat Modares University

##### Expected recruitment start date

2007-01-31, 1385/11/11

##### Expected recruitment end date

2008-01-31, 1386/11/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of Tibolone on cardiovascular disease in menopausal women

##### Public title

Effects of Tibolone on cardiovascular disease in menopausal women

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: healthy non-surgical postmenopausal women (more than one year since the last menstrual period and plasma 17- $\beta$ -estradiol level <35 pg/ml), age 45-60 years . Exclusion criteria: receiving cholesterol-lowering agent, estrogen therapy, antioxidant vitamin supplements during the preceding six months, any contra-indications to HRT, dyslipidemia (cholesterol (CHOL)> 250 mg/dl and/or triglyceride (TG) > 150 mg/dl), smoking, presence of diabetes, previous angina, or hypertension

##### Age

From **45 years** old to **60 years** old

##### Gender

Female

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **150**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic Committee of the Tarbiat Modares University

##### Street address

Jalal Al Ahmad St.

##### City

Tehran

##### Postal code

#### Approval date

2008-03-15, 1386/12/25

#### Ethics committee reference number

150/83441

## Health conditions studied

### 1

#### Description of health condition studied

cardiovascular markers

#### ICD-10 code

Y40

#### ICD-10 code description

Drugs, medicaments and biological substances causing adverse effects in therapeutic use

## Primary outcomes

### 1

#### Description

serum lipid

#### Timepoint

Baseline and after six months

#### Method of measurement

enzymatic method

## Secondary outcomes

### 1

#### Description

CRP

#### Timepoint

Baseline and after six months

#### Method of measurement

immuno turb

### 2

#### Description

BMI

#### Timepoint

at first and after six months

#### Method of measurement

meter weight

### 3

#### Description

SHBG

#### Timepoint

Baseline and after six months

#### Method of measurement

ELISA

### 4

#### Description

FTI

#### Timepoint

Baseline and after six months

#### Method of measurement

ELISA

### 5

#### Description

FEI

#### Timepoint

Baseline and after six months

#### Method of measurement

ELISA

## Intervention groups

### 1

#### Description

Tibolone 2.5mg/daily for 6 months orally

#### Category

Treatment - Drugs

### 2

#### Description

Sulfate estrogen conjugate, 0.625 mg + 2.5 mg medroxy progesterone acetate/daily for six months orally

#### Category

Treatment - Drugs

### 3

#### Description

Calcium 500 mg, Vitamine D (200 IU)/daily for six months orally

#### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Bo Ali Hospital

###### Full name of responsible person

###### Street address

emam hossein squ

###### City

Tehran

#### 2

##### Recruitment center

###### Name of recruitment center

Dr Ziaei's private clinic

###### Full name of responsible person

###### Street address

###### City

Tehran

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Tarbiat Modares University

###### Full name of responsible person

Dr Firozabadi

###### Street address

Jalal Al Ahmad street

###### City

Tehran

##### Grant name

پایان نامه دانشجویی

##### Grant code / Reference number

12/135

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

Yes

##### Title of funding source

Tarbiat Modares University

##### 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

Tarbiat Modares University

##### Full name of responsible person

Dr Saeideh Ziaei

##### Position

Professor

##### Other areas of specialty/work

##### Street address

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##### Web page address

### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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##### Full name of responsible person

Saeideh Ziaei

##### Position

Professor

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### Person responsible for updating data

#### Contact

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##### Full name of responsible person

Dr Saeideh Ziaei

##### Position

professor

##### Other areas of specialty/work

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**Fax****Email****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*