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

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Saeideh Ziaei
Name of organization / entity
Tarbiat Modares University
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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-ß-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 progestrone 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
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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

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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