

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Comparative effects of conventional hormone replacement therapy and tibolone on climacteric symptoms and sexual dysfunction in postmenopausal women

Protocol summary

Summary

The aim of this study was to compare the effect of Tibolone and conventional hormone therapy on climacteric symptoms in postmenopausal women. Inclusion criteria: married, menopause after 40years old and 12 months amenorrhea or 6 month amenorrhea and serum Estradiol less than 50 pg/dl. Exclusion criteria: any history of active hepatitis, cardiovascular, inflammation disease (infectious or uninfected), thromboembolic or cerebrovascular disorder, psychosis, hyper-lipidemia, history of chemotherapy or radiation, HRT treatment in previous 6 months, use of vitamin E, fluoxetine, soy menopause, Propranolol and another herbal or chemical drug, smoking, alcohol or addiction. A total of 154 healthy postmenopausal women with no absolute contraindication for hormone replacement therapy (HRT) were divided into 3 groups: group A: Continuous conjugated estrogen (CE) 0.625mg plus medroxyprogesterone acetate (MPA) 2.5mg (N=48), group B: Tibolone 2.5mg/day (N=53) and group C: placebo group received only Ca-D (500 mg +200 IU) for six months. In this study At baseline and after 6 months of treatment Blood was collected for sex hormone determinations. Climacteric symptoms and Sexual function were assessed by Greene Climacteric Scale and Female Sexual Function Index (FSFI) respectively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809032766N1**

Registration date: **2010-04-26, 1389/02/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-04-26, 1389/02/06

Registrant information

Name

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Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 17 1443 0354

Email address

moghassemi-s@parastari.gehd.org

Recruitment status

Recruitment complete

Funding source

Tarbiat Maodares University

Expected recruitment start date

2006-12-22, 1385/10/01

Expected recruitment end date

2008-08-21, 1387/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effects of conventional hormone replacement therapy and tibolone on climacteric symptoms and sexual dysfunction in postmenopausal women

Public title

Comparative effects of 2 types of hormone replacement therapy on climacteric symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: married, menopause after 40 years old and 12 months amenorrhea or 6 month amenorrhea and serum Estradiol less than 50 pg/dl. Exclusion criteria: any history of active hepatitis, cardiovascular, inflammation disease (infectious or uninfected), thromboembolic or cerebrovascular disorder, psychosis, hyperlipidemia, history of chemotherapy or radiation, HRT treatment in previous 6 months, use of vitamin E, flutamide, soy menopause, propranolol and another herbal or chemical drug, smoking, alcohol or addiction

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tarbiat Modares University

Street address

Jalal Ale Ahmad Highway

City

Tehran

Postal code

Approval date

empty

Ethics committee reference number

64983/50

Health conditions studied

1

Description of health condition studied

menopause

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

climacteric symptom

Timepoint

6 month

Method of measurement

Greene Climacteric Scale & Female Sexual Function Index

Secondary outcomes

1

Description

sex hormone status & sex hormone-binding globulin (SHBG)

Timepoint

6 month

Method of measurement

biochemistry

Intervention groups

1

Description

group A: Continuous conjugated estrogen (CE) 0.625mg plus medroxyprogesterone acetate (MPA) 2.5mg

Category

Treatment - Drugs

2

Description

group B: Tibolone 2.5mg/day

Category

Treatment - Drugs

3

Description

group C (placebo group): Ca-D (500 mg +200 IU)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fajr & Boali hospitals, Shahid Haidari & Aboraihan

polyclinics, a private clinic
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tarbiat Maodares University
Full name of responsible person
Dr. Yaghoub Fatolahi
Street address
Jalal Ale Ahmad Highway
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tarbiat Maodares 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

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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