Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 uninfectious), thoromboambolic 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 medroxyprogestrone 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)

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moghasemi-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, inflamation disease (infectious or uninfectious), thoromboambolic or cerebrovascular disorder, psychosis, hyperlipidemia, history of chemotherapy or radiation, HRT treatment in previous 6 months, use of vitamine E, fluxitine, soymenopause,propranolol and another herbal or chemical druge, smoking, alchol 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 medroxyprogestrone 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

City

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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

Person responsible for general inquiries

Contact

Name of organization / entity

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Position

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City

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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