

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effects of HRT on cognitive function in postmenopausal women

Protocol summary

Summary

A total of 140 postmenopausal women aged between 48 to 58 years old are randomly assigned to two groups of 70 subjects; group 1 receive traditional HRT with calcium + vitamin D tablet and group 2 receive only calcium + vitamin D tablet. The cognitive function of the women are considered by MOCA questionnaire before and after 6 months and are compare between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604043743N2**
Registration date: **2016-07-12, 1395/04/22**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-12, 1395/04/22

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, Jalal Al Ahmad street Tehran
Iran

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2017-02-18, 1395/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of HRT on cognitive function in
postmenopausal women

Public title

The effects of HRT on cognitive function

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: natural menopause; maximum 10 years from menopause, without any contraindication for hormone therapy; no HRT in previous 6 months; without any chronic disease such as cancer psychological diseases; no addiction or smoking; no hyperplasia or myoma in the uterus.

Age

From **48 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

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

Tarbiat Modares University

Street address

Tarbiat Modares University, Jalal Al Ahmad street

City

Tehran

Postal code

14115315

Approval date

2013-12-11, 1392/09/20

Ethics committee reference number

52/5000

Health conditions studied

1

Description of health condition studied

Cognitive dysfunction

ICD-10 code

F06.7

ICD-10 code description

Mild cognitive disorder

Primary outcomes

1

Description

Cognitive function

Timepoint

After 6 months

Method of measurement

MOCA questionnaire

Secondary outcomes

1

Description

Climacteric symptom

Timepoint

After 6 months

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group 1: HRT and calcium +D tablet (0.625 mg conjugated estrogen plus 2.5 mg medroxy progesterone +calcium D 500 mg + 200 IU vitamin D) daily for six months

Category

Treatment - Drugs

2

Description

Intervention group 2: Calcium +vitamin D tablet (500mg calcium+200 IU vitamin D) daily for six months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat 1, 2 clinics

Full name of responsible person

Street address

City

Kerman

2

Recruitment center

Name of recruitment center

Dr. Ziaei 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. Movaheddin

Street address

Tarbiat Modares University, Jalal Al Ahmad St.

City

Tehran

Grant name

Grant code / Reference number

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

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Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

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Saeideh Ziaei

Position

Professor

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Position

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Other areas of specialty/work**Street address**

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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