Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 cojugated estrogen plus 2.5 mg medroxy progestron +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

Person responsible for general inquiries

Contact
Name of organization / entity
Tarbiat Modares University
Full name of responsible person
Saeideh Ziaei
Position
Professor
Other areas of specialty/work
Street address
Tarbiat Modares University, Jalal Al Ahmad street
City
Tehran
Postal code
39
Phone
+98 21 8288 3555
Fax
+98 82883585
Email
ziaei_sa@modares.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tarbiat Modares University
Full name of responsible person
Saeideh Ziaei
Position
Professor
Other areas of specialty/work
Street address
Tarbiat Modares University, Jalal Al Ahmad street
City
Tehran
Postal code
Phone
+98 21 8288 3555
Fax
Email
ziaei_sa@modares.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tarbiat Modares Univrersity
Full name of responsible person
Saeideh Ziaei
Position
Prof
Other areas of specialty/work
Street address
Jalal al ahmad street
City
tehran
Postal code
14115111
Phone
+98 21 8288 3555
Fax
+98 21 8288 4560
Email
ziaei_sa@modares.ac.ir
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