

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### the effect of Ginkgo biloba on sexual dysfunction in women with breast cancer compared with placebo

#### Protocol summary

##### Summary

The proposed study will evaluate a Ginkgo biloba intervention (compared to placebo) on female sexual function. In this double-blind, randomized, placebo-controlled trial, 60 women, with hormone-receptor-negative breast cancer who had undergone breast cancer surgery will be enrolled. Any participant who consume anticoagulant agents, psychopharmacological drugs or have any serious medical conditions, and not having sex at least twice during the study period will be excluded. Women will randomly, using a computer-generated code, assign to receive Ginkgo biloba or placebo for 8-weeks. The intervention group will receive a pill of Ginkgo biloba (40 mg), three times a day for 2 weeks. Participants who tolerate the pills will receive them at a dose of 80 mg three times a day for the remainder of the study. The control group will receive pills of placebo, following the same regimen as the Ginkgo biloba group. The score of Female Sexual Function Index (FSFI) would be the primary outcome measure that will be assessed before and after intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016012414477N3**

Registration date: **2016-03-09, 1394/12/19**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-03-09, 1394/12/19

##### Registrant information

###### Name

Zhila Taherzadeh

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1882 3255

##### Email address

taherzadehzh@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University of Medical Sciences, Vice Chancellor for Research

##### Expected recruitment start date

2016-03-20, 1395/01/01

##### Expected recruitment end date

2016-10-14, 1395/07/23

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

the effect of Ginkgo biloba on sexual dysfunction in women with breast cancer compared with placebo

##### Public title

The Effect of Ginkgo biloba on sexual dysfunction in patients with breast cancer; A randomized double blind placebo - controlled clinical trial

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Being married;18 years of age or older; At least 2 month after the end of treatment; Signed and dated written informed consent prior to admission to the study;The ability to speak; understand the Persian;

Patients who had undergone breast cancer surgery  
Exclusion criteria: not having sex at least twice during the study period; Having any other medical conditions such as: cardiovascular diseases ( i.e. uncontrolled hypertension, history of infarction, deep-vein thrombosis), Pulmonary diseases (i.e. asthma, shortness of breath), Neurological diseases ( i.e. convulsions, epilepsy, migraine, cerebrovascular disorder), History of bleeding disorder, kidney diseases, liver diseases, endocrine disorders (i.e. diabetes), mental disorders, coagulation disorders; Other malignancies other than breast cancer; Infertility; Stressful event (other than cancer) during the last 6 months (e.g. traumatic and stressful event, changes in living conditions such as relocation, financial ruin, marital problems, losing a close family member); Failing to follow the treatment plan; A history of psychiatric disorder; Patients taking SSRI 2 weeks prior to study; Anticoagulant therapy (Heparin, enoxaparin, warfarin, clopidogrel, ticlopidine) 2 weeks prior to study; Patients with hormone-receptor (HR)-positive breast cancer.

**Age**

From **18 years** old to **80 years** old

**Gender**

Female

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **52**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Regional Committee for Research Ethics, Mashhad  
University of Medical Sciences

**Street address**

Ghoreishi building, Daneshgah Street

**City**

Mashhad

**Postal code****Approval date**

2015-12-19, 1394/09/28

**Ethics committee reference number**

IR.MUMS.REC.1394.577

**Health conditions studied****1****Description of health condition studied**

breast cancer

**ICD-10 code**

c50

**ICD-10 code description**

Family history of malignant neoplasm of breast

**Primary outcomes****1****Description**

Female Sexual Function Index score

**Timepoint**

Before and after intervention

**Method of measurement**

Female Sexual Function Index scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

The intervention group will receive a pill of Ginkgo biloba (40 mg), three times a day for 2 weeks. Participants who tolerate the pills will receive them at a dose of 80 mg three times a day for the remainder of the study

**Category**

Treatment - Drugs

**2****Description**

The control group will receive pills of placebo that look like Ginkgo biloba tablet, following the same regimen as the intervention group.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Emam Reza Hospital

**Full name of responsible person**

Fatemeh Homaei Shandiz

**Street address**

Emam Reza Square, Ebne Sina Avenue

**City**

Mashhad

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### Recruitment center

**Name of recruitment center**

Ghaem Educational, Research and Treatment Center

**Full name of responsible person**

Fatemeh Homae Shandiz

**Street address**

Dr. Shariati Square, beginning of Ahmadabad Avenue

**City**

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## 3

### Recruitment center

**Name of recruitment center**

Omid Hospital

**Full name of responsible person**

Azar Fani Pakdel

**Street address**

Alandasht Square, Koohsangi Avenue

**City**

Mashhad

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### Recruitment center

**Name of recruitment center**

Reza Radiotherapy Oncology Center (RROC)

**Full name of responsible person**

Azar Fani Pakdel

**Street address**

Fallahi 2, Ghasemabad

**City**

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences, Vice chancellor for research

**Full name of responsible person**

Dr. Mohsen Tafaghodi (Research Deputy of Mashhad University of Medical Sciences)

**Street address**

University St., Ghoraihy Building

**City**

Mashhad

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad University of Medical Sciences, Vice chancellor for research

**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**

Cancer Research Center, Mashhad University of Medical Sciences, Mashhad, Iran

**Full name of responsible person**

Fatemeh Homae Shandiz

**Position**

Associate Professor

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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*