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)

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+98 51 1882 3255

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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 Homaee Shandiz

Street address
Emam Reza Square, Ebne Sina Avenue

City

Mashhad

2

Recruitment center
Name of recruitment center
Ghaem Educational, Research and Treatment Center
Full name of responsible person
Fatemeh Homaee Shandiz
Street address
Dr. Shariati Square, beginning of Ahmadabad Avenue
City
Mashhad

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

4

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., Ghoraishy 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 Homaee Shandiz
Position
Associate Professor
Other areas of specialty/work
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Omid Hospital, Alandash Square, Koohsangi Avenue
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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