Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effect of Zinc supplementation on sexual satisfaction, sexual function and testosterone level in postmenopausal women

Protocol summary

Study aim
The effect of zinc supplementation on satisfaction, sexual function and testosterone levels in postmenopausal women

Design
The study is a clinical trial performed 116 people and two intervention and control groups

Settings and conduct
The study was conducted on population referred to the Menopause clinic of Imam Khomeini hospital in Ahvaz Menopause ; these patents were first evaluated by FSFI and Larson questionnaire and voluntarily entered the study. Subjects were given a diet for six weeks Post-test was completed after six weeks

Participants/Inclusion and exclusion criteria
Married, literate, 49 years of age, post menopausal, FSFI less than 26.5 and Larson less than 50 and on plasma less than 62 and People who did not have entry criteria excuded

Intervention groups
Two groups of intervention and control group intake Zink supplementation 110 mg for six weeks in the intervention and placebo in the control group

Main outcome variables
Postmenopausal Sexual Function and Satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191007045010N1**
Registration date: **2019-11-27, 1398/09/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-27, 1398/09/06**
Update count: **0**

Registration date
2019-11-27, 1398/09/06

Registrant information

Name
Leila Mazaherinia

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-07, 1398/07/15

Expected recruitment end date
2020-01-05, 1398/10/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Zinc supplementation on sexual satisfaction, sexual function and testosterone level in postmenopausal women

Public title
The effect of Zinc supplementation on sexual satisfaction, sexual function and testosterone level in postmenopausal women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Married women At least one year and a maximum of 5

years since the last menstrual period Minimum literacy 49 years and up People whose FSFI score is <26.5 Those who achieved according ton Larsson questionnaire of sexual dissatisfaction (score of 50 and below), low sexual satisfaction (score of 51-75) People whose fasting plasma zinc is less than 62 micrograms / dL

Exclusion criteria:

Having at least one known chronic illness Current experience of mental disorders and depression in the sample of the researcher and his wife Addiction, alcohol abuse and smoking Drugs affecting sexual function Those who use replacement hormones

Age

From **49 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Both the research sample and the experimenter do not know which sample (control or intervention) the sample is in.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Medical Sciences Ethics Committee

Street address

No.6/415، Nine Bahar steet، Abadan

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Ahwaz

Province

Khouzestan

Postal code

6315733653

Approval date

2019-09-28, 1398/07/06

Ethics committee reference number

IR. AJUMS. REC. 1398. 466

Health conditions studied

1

Description of health condition studied

Postmenopausal Sexual Disorders

ICD-10 code

F66

ICD-10 code description

Other sexual disorders

Primary outcomes

1

Description

Sexual Function: A set of sexual responses and reactions including sexual desire, satisfaction, vaginal lubrication, orgasm and pain in sexual intercourse with the spouse, which is determined by the Sexual Function Index Questionnaire with a FSFI score greater than or equal to 26.5 Desirable Sexual Function and FSFI score less than 26.5 is considered sexual dysfunction and people with FSFI score less than 26.5 are included in the study

Timepoint

Day zero and 43

Method of measurement

FSFI questionnaire

2

Description

Sexual satisfaction: means the objective feelings of satisfaction, satisfaction, and enjoyment experienced by a spouse when considering all aspects of their marriage. Persons who, according to the Larsson Questionnaire of Sexual dissatisfaction (score 50 and below), low sexual satisfaction (score51-75) they enter the study

Timepoint

Day zero and 43

Method of measurement

Larson questionnaire

Secondary outcomes

1

Description

Testosterone levels

Timepoint

Before the study and day 43

Method of measurement

The radioimmunoassay method

Intervention groups

1

Description

Intervention group:intake of Zink Sulfate capsule 110 mg Alhavi Pharmaceutical Company daily for 42 days

Category

Treatment - Drugs

2

Description

Control group:Intake placebo daily for 42 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr. Mina Irvani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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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

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Leila Mazaheri nia

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable