

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

Comparison of the effect of zinc and vitamin C supplementation with placebo on performance and sexual satisfaction of nulliparous women

Protocol summary

Study aim

Determining the effect of zinc and vitamin C supplement capsules on performance and sexual satisfaction of nulliparous women

Design

A randomized controlled trial clinical trial with parallel, three-blind, randomized groups.

Settings and conduct

This study is performed in gynecological clinics and health centers affiliated with Arak University of Medical Sciences. Samples will be selected from nulliparous women. Then, they are randomly divided into two groups of intervention and control. The intervention group is given capsules containing 10 mg of zinc and 300 mg of vitamin C daily for 4 weeks. The control group is given a capsule containing starch daily as a placebo for 4 weeks. The study is done in three blinds.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study, ages 18 to 50, nulliparous women who are 2 weeks after giving birth, Score less than 28 in the Sexual Function Questionnaire. Exclusion criteria: Any disorders caused by pregnancy.

Intervention groups

Group 1 (intervention): Capsules containing 10 mg of zinc and 300 mg of vitamin C are given daily for 4 weeks. Group 2 (placebo): Capsules containing starch are given as a placebo daily for 4 weeks.

Main outcome variables

Sexual performance and satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130731014229N12**

Registration date: **2021-02-23, 1399/12/05**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-23, 1399/12/05**

Update count: **0**

Registration date

2021-02-23, 1399/12/05

Registrant information

Name

Hadi Jafari manesh

Name of organization / entity

Arak University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3503

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jafarimanesh@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-29, 1399/11/10

Expected recruitment end date

2021-09-01, 1400/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of zinc and vitamin C supplementation with placebo on performance and sexual satisfaction of nulliparous women

Public title

The effect of zinc and vitamin C supplementation on sexual function and satisfaction nulliparous women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

nulliparous women who have passed 2 weeks after giving birth Age is between 18 and 50 years Have informed consent to study Score less than 28 in the sexual function questionnaire.

Exclusion criteria:

Any disorders caused by pregnancy

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples are randomly assigned to quadruple blocks A, A, B, B in random groups. So that 20 blocks of 4 letters A and B are made up. Then a block is randomly selected. RAS random allocation software will be used to randomly select blocks. A indicates sample placement in intervention group and B indicates sample placement in control group. First, a block will be randomly identified by RAS software and then the first eligible sample will be entered into the intervention or control group according to the order of the letters A or B. Sampling will continue until all samples are selected.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants, principal researcher and data analyzer do not know which groups are located. The samples in the intervention and control group did not know whether they received the placebo or the main drug. The statistician will receive questionnaires as anonymously and in form A and B, and he does not know which are intervention and control group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Basij Sq.

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2020-12-13, 1399/09/23

Ethics committee reference number

IR.ARAKMU.REC.1399.279

Health conditions studied

1

Description of health condition studied

Performance and sexual satisfaction of nulliparous women

ICD-10 code

F52.9

ICD-10 code description

Unspecified sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description

Women's sexual function score

Timepoint

Before the intervention and four weeks after the intervention

Method of measurement

Women's Sexual Function Questionnaire

2

Description

Women's sexual satisfaction score

Timepoint

Before the intervention and four weeks after the intervention

Method of measurement

Multidimensional scale of women's sexual satisfaction

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Capsules (Omid Health Supplement Company) containing 10 mg of zinc and 300 mg of vitamin C are given daily for 4 weeks. The intervention is

performed for patients who have not received any treatment for their problem.

Category

Treatment - Drugs

2

Description

Control group: Capsules containing starch (Niko Shimi Company) are given daily as a placebo for 4 weeks. The intervention is performed for patients who have not received any treatment for their problem.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecology Clinic of Arak University of Medical Sciences

Full name of responsible person

Hadi Jafarianesh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

n;jv

Street address

Deputy of Research and Technology, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

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Phone

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Email

alikamaliir@yahoo.com

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Hadi Jafarianesh

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

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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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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