

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of *Saccharomyces Cerevisiae* enriched with selenium and mineral selenium on postpartum depression and sexual satisfaction: A triple-blind randomized controlled trial

Protocol summary

Study aim

Comparison of the effect of *Saccharomyces Cerevisiae* enriched with selenium and mineral selenium on postpartum depression and sexual satisfaction

Design

The present study is a controlled trial, phase 3, with three parallel groups, triple blind, which will be performed on 108 people in three groups. The research environment will be the health centers of Tabriz city.

Settings and conduct

This study will be performed in health centers in Tabriz. A member of the non-research team involved in the selection of samples will determine the random allocation sequence using a computer program. Closed opaque envelopes will be used numbered in order to conceal the allocation. Eligible individuals will be randomly assigned to three groups using block sizes of 3 and 6 blocks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women 18 years and older, Recent low-risk pregnancies, Having a care record at the nearest health center
Exclusion criteria: Existence of prenatal depression, A score above 23 on the Edinburgh Questionnaire, History of depression or any other mental disorder, Death or hospitalization of the baby in the intensive care unit, Stillbirth, Hospitalization of the mother due to postpartum complications, Having chronic diseases such as liver and kidney disease, Having frequent miscarriages and having a history of infertility, Having a history of a child with a mental or physical disability, Allergy to fungi and yeast

Intervention groups

In this study, two groups will receive mineral selenium and *Saccharomyces Cerevisiae* enriched with selenium as the intervention groups and the third group will receive placebo as the control group.

Main outcome variables

Score of depressive symptoms before and after the intervention, Score of sexual satisfaction before and after the intervention.

General information

Reason for update

Acronym

مقایسه تاثیر مخمر ساکارومایسس سروزیه غنی شده با سلنیوم و سلنیوم معدنی بر افسردگی بعد از زایمان و میزان رضایت جنسی

IRCT registration information

IRCT registration number: **IRCT20110606006709N23**

Registration date: **2021-09-13, 1400/06/22**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-13, 1400/06/22**

Update count: **0**

Registration date

2021-09-13, 1400/06/22

Registrant information

Name

Mahnaz Shahnazi

Name of organization / entity

Tabriz University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-02, 1400/05/11

Expected recruitment end date

2021-11-30, 1400/09/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Saccharomyces Cerevisiae enriched with selenium and mineral selenium on postpartum depression and sexual satisfaction: A triple-blind randomized controlled trial

Public title
The effect of Saccharomyces Cerevisiae enriched with selenium and mineral selenium on postpartum depression and sexual satisfaction

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women over 18 years who are in the first 15 to 90 days after giving birth. Willingness to participate in research
Having a record of care in health centers
Exclusion criteria:
A score above 23 on the Edinburgh Questionnaire History of depression or any other mental disorder Death or hospitalization of the baby in the intensive care unit Stillbirth Hospitalization of the mother due to postpartum complications Having chronic diseases such as liver and kidney disease Allergy to fungi and yeast Loss of loved ones between two months before delivery and two months after delivery Having frequent miscarriages and having a history of infertility Having a history of a child with a mental or physical disability Divorce over the past three months

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **108**
More than 1 sample in each individual
Number of samples in each individual: **36**
Target sample size: 108

Randomization (investigator's opinion)
Randomized

Randomization description
Breastfeeding women with mild to moderate depression scores using a randomized blocking method with a size of three or six blocks using RAS (Random Allocation

Software) with a 1: 1: 1 allocation ratio in The three groups receiving Saccharomyces cerevisiae enriched with selenium, mineral selenium and placebo will be included. To hide the allocation, the group name will be placed inside a numbered consecutive matte envelope. Envelope preparation and random allocation sequencing will be performed by the non-research person.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The drugs and their placebo will be prepared by the pharmaceutical company in a completely similar way in terms of shape, color and smell. The researcher, participants, data analyst, and outcome reviewer are unaware of the type of intervention received.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Approval date

2021-07-05, 1400/04/14

Ethics committee reference number

IR. TBZMED.REC.1400.342

Health conditions studied

1

Description of health condition studied

Postpartum Depression

ICD-10 code

O90.6

ICD-10 code description

Postpartum mood disturbance

Primary outcomes

1

Description

Depression score

Timepoint

Before and after the intervention at intervals of 8 weeks

Method of measurement

Edinburgh Depression Inventory

2

Description

Sexual satisfaction

Timepoint

Before and after the intervention at intervals of 8 weeks

Method of measurement

Sexual Satisfaction Questionnaire

Secondary outcomes

1

Description

Side events

Timepoint

During 8 weeks of intervention

Method of measurement

Side accident assessment form

Intervention groups

1

Description

Intervention group 1: Capsules containing Saccharomyces Cerevisiae enriched with selenium 200 micrograms, one for 8 weeks. Drugs will be made in the Faculty of Nutrition of Tabriz University of Medical Sciences by the Department of Pharmacy Dr. Ostad Rahimi

Category

Treatment - Drugs

2

Description

Intervention group 2: Capsules containing mineral selenium 200 micrograms, one for 8 weeks. Drugs will be made in the Faculty of Nutrition of Tabriz University of Medical Sciences by the Department of Pharmacy Dr. Ostad Rahimi.

Category

Treatment - Drugs

3

Description

Control group: Capsules containing placebo, one for 8 weeks. Placebo will be made in the Faculty of Nutrition of Tabriz University of Medical Sciences by the Department of Pharmacy Dr. Ostad Rahimi.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers selected in Tabriz

Full name of responsible person

Parnyan Rahimi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Parnian Rahimi
Position
Student of master's degree in Midwifery
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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