Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effects of probiotic supplementation and placebo on clinical status and metabolic profiles in overweight or obese women with fibrocystic changes of breast

Protocol summary

Study aim

The aim of this study is to determine the effects of probiotic supplementation on clinical status and metabolic profiles in overweight or obese women with fibrocystic changes of breast

Design

Study design: Randomized double-blind placebo-controlled trial. Patients will be assigned into two groups to receive probiotic supplements (n=25) or placebo (n=25).

Settings and conduct

Among women with fibrocystic changes of breast who are referred to Beheshti Clinic affiliated to Kashan University of Medical Sciences, 50 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. intervention period: 12 weeks

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18-45 years diagnosed with fibrocystic breast disease, having moderate or severe cyclic mastalgia, BMI ≥ 25. Exclusion criteria: Malignant breast diseases, taking medicines for reducing pain (such as danazol, tamoxifen, bromocriptine) over the past three months, menopause women, pregnant or breastfeeding women, psychological diseases, Unwillingness to cooperate

Intervention groups

Intervention group: Probiotic capsule (Zisttakhmir Co., Tehran, Iran), including 2×109 Lactobacillus acidophilus, 2×109 Bifidobacterium bifidum, 2×109 Lactobacillus reuteri, 2×109 Lactobacillus fermentum, once a day for 12 weeks orally. Control group: Placebo capsules (Zisttakhmir Co., Tehran, Iran), once a day for 12 weeks orally.

Main outcome variables

hs-CRP (primary outcome) and Breast Pain Severity, biomarkers of oxidative stress, parameters of mental health, glucose and lipid metabolism indices (secondary outcomes)

General information

Reason for update

The updating process was done before publishing the paper to correct the registration information.

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N68**
Registration date: **2020-04-05, 1399/01/17**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-11, 1399/01/23**
Update count: **1**

Registration date

2020-04-05, 1399/01/17

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5546 3378

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ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-05, 1398/12/15

Expected recruitment end date
2020-07-05, 1399/04/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effects of probiotic supplementation and placebo on clinical status and metabolic profiles in overweight or obese women with fibrocystic changes of breast

Public title
Effects of melatonin supplementation in the treatment of fibrocystic changes of breast
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18-45 years women diagnosed with fibrocystic breast disease having moderate or severe cyclic mastalgia BMI ≥ 25
Exclusion criteria:
Malignant breast diseases Taking medicines for reducing pain (such as danazol, tamoxifen, bromocriptine) over the past three months Menopause women Pregnant or breastfeeding women Psychological diseases Unwillingness to cooperate
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned into two groups. A randomization list will be generated from 1 to 50 by a random number generator (https://stattrek.com/statistics/random-number-generator.aspx) and patients were randomly assigned into each intervention group by their numbers. The block randomization technique with 1:1 ratio will be used to achieve balanced group sizes.
Blinding (investigator's opinion)
Double blinded
Blinding description
Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the general surgery clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules. Supplements and placebo are in the same packaging at the Zisttakhmir pharmaceutical company. Only the code is written on the packages. Patients and researcher will not know the type of drug. After analyzing the data, packet codes will be decoded. Participants, investigators or the assessors of the outcomes are unaware of the study groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Approval date
2020-02-03, 1398/11/14
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1398.127

Health conditions studied

1

Description of health condition studied
Breast fibrocystic disease
ICD-10 code
N60
ICD-10 code description
Benign mammary dysplasia

Primary outcomes

1

Description
high-sensitivity C-reactive protein (hs-CRP)
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

Secondary outcomes

1

Description
Breast Pain Severity
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Visual analogue scale 0-10

2

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

3

Description
Glutathione
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

4

Description
Total antioxidant capacity
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

5

Description
Triglycerides
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

6

Description
Total cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

7

Description
HDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

8

Description
Insulin
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

9

Description
Insulin resistance
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Calculation using HOMA formula

10

Description
Depression score on Beck Depression Inventory
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

11

Description
Anxiety score on Beck Anxiety Inventory
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

12

Description
Sleep Quality score on Pittsburgh Sleep Quality Index
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Probiotic capsule (Zisttakhmir Co., Tehran, Iran), including 2×109 Lactobacillus acidophilus, 2×109 Bifidobacterium bifidum, 2×109 Lactobacillus reuteri, 2×109 Lactobacillus fermentum, once a day for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo capsules (Zisttakhmir Co., Tehran, Iran), once a day for 12 weeks orally.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Clinic
Full name of responsible person
Dr. Abdoulhossein Davoodabadi
Street address
Ghotbe Ravandi Boulevard, Kashan
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davoodabadi_ab@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Hamidreza Banafshe
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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
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Dr. Seyed Hamed Rouhani
Position
Resident of general surgery
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Person responsible for updating data

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Medical doctor
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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