Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study of the effect of synbiotic supplementation on pregnancy outcomes in mothers with mild preeclampsia : A triple blind randomized controlled trial

Protocol summary

Study aim

1- Comparison of maternal outcomes in two groups of synbiotic and placebo recipients in women with mild preeclampsia. 2- Comparison of neonatal outcomes in two groups of synbiotic and placebo recipients in women with mild preeclampsia.

Design

Controlled clinical trial, Phase 3, with two groups of parallel, three-blind

Settings and conduct

This study will be conducted in Al-Zahra and Taleghani hospitals in Tabriz. A non-involved research team member in the sample selection will determine the random allocation sequence using a computer program. Opaque envelopes in sealed numbered order will be used to hide the allocation. Eligible individuals will be randomly assigned to two groups of 64 individuals, first by simple method and then by blocking with block sizes of 4 and 6.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Detection of mild preeclampsia 2) Singleton pregnancy with live fetus 3) Gestational age more than 24 weeks 4) Women with first pregnancy (Nullipar) 5) Suitable maternal and fetal conditions for expectant management Exclusion criteria: 1) Women with cardiovascular disease 2) Women with renal and hepatic dysfunction 3) Severe and chronic hypertension 4) Gestational diabetes mellitus and chronic 5) History of probiotic susceptibility 6) Use of antibiotics over the past two weeks

Intervention groups

Intervention group:The intervention group of the LactoCare synbiotic capsule made by the "Zist-takhmir" company, which contains the highest amounts of beneficial bacteria along with peribiotic fructologosaccharide (contributing to the growth and activity of probiotics). Control group: Participants in this group will receive a placebo capsule quite similar to the synbiotic capsule.

Main outcome variables

Mean systolic and diastolic blood pressure؛ The average length of pregnancy from diagnosis to delivery؛ Average birth weight at two groups.

General information

Reason for update

the Sampling to be too long due to the onset of Covid-19 virus prevalence, Change the first author's little name from Rouhangiz to Rouhina

Acronym

IRCT registration information

IRCT registration number: **IRCT20110606006709N20**
Registration date: **2019-09-25, 1398/07/03**
Registration timing: **prospective**

Last update: **2022-08-13, 1401/05/22**
Update count: **2**

Registration date

2019-09-25, 1398/07/03

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
2019-10-22, 1398/07/30
Expected recruitment end date
2020-05-19, 1399/02/30
Actual recruitment start date
2019-11-12, 1398/08/21
Actual recruitment end date
2022-12-21, 1401/09/30
Trial completion date
2022-12-21, 1401/09/30

Scientific title
Study of the effect of synbiotic supplementation on pregnancy outcomes in mothers with mild preeclampsia : A triple blind randomized controlled trial

Public title
The effect of probiotic supplementation on pregnancy outcomes in mothers with mild preeclampsia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women with mild preeclampsia singleton pregnancy with live fetus Gestational age more than 24 weeks Women with first pregnancy (Noliparus) Suitable maternal and fetal conditions for expectant management
Exclusion criteria:
Women with cardiovascular disease Women with renal and hepatic dysfunction Extreme and chronic hypertension Gestational diabetes mellitus and chronic History of probiotic susceptibility Use of antibiotics over the past two weeks
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

Sample size
Target sample size: **128**
Actual sample size reached: **128**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly assigned into two groups of recipients of training or control using random blocking method and blocks of size 4 and 6 using Random Allocation Software (RAS) with a 1: 1 assignment ratio by the person not involved in the research. To conceal the allocation, opaque envelopes with sample numbers will be provided and numbered. Preparation of envelopes and sequence generation will be done by a person not involved in the research.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, The drug and the placebo will be prepared by the same pharmaceutical company in identical shape, color and smell. participants, researchers, medical staff (doctors, nurses, etc.) who are responsible for patient care, data collection officers and those who evaluate the outcome will not be informed about the drug type. To number of samples, large envelopes will be provided and flaccons will be placed inside the envelopes. Each packet will be assigned a number from 1 to 128 numbers. The envelopes are uniform, sealed, opaque and contain 14 capsules. And preparing them according to the allocation sequence will be done by the person not involved in the research.
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
South Shariati Street, College of Nursing and Midwifery
City
Tabtiz
Province
East Azarbaijan
Postal code
5138947977
Approval date
2019-08-19, 1398/05/28
Ethics committee reference number
IR.TBZMED.REC.1398.556

Health conditions studied

1

Description of health condition studied
mild preeclampsia
ICD-10 code
O14.0
ICD-10 code description
Mild to moderate pre-eclampsia

Primary outcomes

1

Description
Mean systolic and diastolic blood pressure
Timepoint
Blood pressure will be measured before, during and after the study.
Method of measurement
Measurement of blood pressure by ISOMED mercuric barometric device

2

Description
Mean duration of pregnancy from diagnosis to delivery.
Timepoint
A the time of delivery
Method of measurement
Duration of pregnancy by calculating LMP or first trimester ultrasound

3

Description
Mean of newborn weight at birth
Timepoint
A the time of delivery
Method of measurement
Measurement of birth weight by SECA scales

Secondary outcomes

1

Description
Detection of severe preeclampsia
Timepoint
During the study
Method of measurement
Criteria for the diagnosis of severe preeclampsia in the questionnaire

Intervention groups

1

Description
Intervention group:The intervention group of the LactoCare synbiotic capsule made by the "Zist-takhmir" company, which contains the highest amounts of beneficial bacteria (lactobacilli, bifidobacteria and streptococcus), along with peribiotic fructologosaccharide (contributing to the growth and activity of probiotics).
Category
Treatment - Drugs

2

Description
Control group: Participants in this group will receive a placebo capsule quite similar to the synbiotic capsule.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra teaching - medical center
Full name of responsible person
Rouhina Movaghar
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2

Recruitment center
Name of recruitment center
Taleghani teaching - medical center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Abolghasem Jooybani
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Research department, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

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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
Rouhina Movaghar

Position
Msc Student of Midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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Mahnaz Shahnazi

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Associate professor

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Person responsible for updating data

Contact

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Position
Master of sciences student of Midwifery

Latest degree
Bachelor

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

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