

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The impact of oral probiotics on vaginal Group B Streptococcal colonization rates on Group B Streptococcus (GBS)-positive pregnant women

Protocol summary

Study aim

Determining the effect of the probiotic supplement on the rate of vaginal colonization of GBS in pregnant women with group B streptococcus

Design

A clinical trial with the control group, with parallel groups, double-blind, randomized, phase 3 on 64 pregnant women with group B streptococcus. Sealed envelope software is used for randomization.

Settings and conduct

This study will evaluate the Familact effect on GBS in pregnant women referred to Al-Zahra Hospital. In the Intervention group, patients will receive 1 capsule of 500 mg Familact for 1 month. The supplement constituents 7 strains. Familact is a probiotic from Zist Takhmir Company consisting of 109 probiotic units. In the Control group, patients will receive 1 capsule of placebo with the same smell and taste as Probiotic supplement for one 1 month. Sampling was performed by the blocking randomization method. Women will be randomly assigned with 4 and 6 block sizes with 1:1 allocation to the two groups of intervention and control. Double Blinding will be performed for participants and Researchers.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patient consent to participate, Pregnant women > 18 years of age who are diagnosed with GBS, Having a positive culture, Gestational age 36 weeks and less Exclusion Criteria: Preeclampsia or gestational diabetes or other diseases, Termination of pregnancy < 38 weeks, Absolute bed rest of the patient

Intervention groups

Intervention group: Patients will receive 1 capsule of 500 mg Familact for 1 month. The supplement constituents 7 strains. Familact is a probiotic from Zist Takhmir Company consisted of 109 probiotic units. Control group: Patients will receive 1 capsule of placebo

with the same texture as a Probiotic supplement for 1 month

Main outcome variables

Frequency of group B streptococcus at the end of one month

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211012052737N1**

Registration date: **2021-11-02, 1400/08/11**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-02, 1400/08/11**

Update count: **0**

Registration date

2021-11-02, 1400/08/11

Registrant information

Name

Elham Tooti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2086

Email address

drelhamtooty.inf@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of oral probiotics on vaginal Group B
Streptococcal colonization rates on Group B
Streptococcus (GBS)-positive pregnant women

Public title

The impact of oral probiotics on vaginal Group B
Streptococcal colonization rates on Group B
Streptococcus (GBS)-positive pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient consent to participate in this study Pregnant women over 18 years of age who are diagnosed with GBS based on physical examination, clinical and laboratory signs. Having a positive culture of vaginal / rectal secretions for group B streptococci Gestational age 36 weeks and less

Exclusion criteria:

Preeclampsia or gestational diabetes or other diseases
Termination of pregnancy earlier than 38 weeks of gestation Absolute bed rest of the patient Taking antibiotics during the intervention and one week before it

Age

From 18 years old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 64

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done before the start of the program by <https://www.sealedenvelope.com> considering 32 people in each group (2 groups of probiotic and control in 2 simple and complex strata) in 6 blocks. Any of them is placed in a separate envelope according to the list obtained from the software and it will be closed and provided to the third person. Patients' names will be registered by admission. If the patient comes and is qualified, the envelope will be opened and based on the expected sequence, she will be treated.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher and participants are blind in this study (double-blind). The Researcher does not know which participant is in the intervention or control group. The

participant does not know whether he/ she is in the intervention or control group. Both groups will receive capsules with the same shape and color with different contents. Intervention and control capsules will be noted as A and B by a pharmacist unaware of the research and will be given to the researcher.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of School of Medicine -
Isfahan University of Medical Sciences

Street address

hezar jrib

City

isfahan

Province

Isfahan

Postal code

4144444444

Approval date

2020-09-20, 1399/06/30

Ethics committee reference number

IR.MUI.MED.REC.1399.513

Health conditions studied**1****Description of health condition studied**

Streptococcus group B in pregnant women

ICD-10 code

099.820

ICD-10 code description

Streptococcus B carrier state complicating pregnancy

Primary outcomes**1****Description**

frequency of group B streptococcus

Timepoint

1 month after intervention

Method of measurement

Positive culture test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pregnant women will receive one 500 mg Familact capsule for 1 month. The supplement constituents 7 strains (Lactobacillus Casei, Lactobacillus Rhamnosus, Streptococcus thermophiles, Bifidobacterium brevis, Lactobacillus acidophilus, Bifidobacterium lehman, Lactobacillus bulgaricus). Familact is from Zist Takhmir Company consisted of 109 probiotic units.

Category

Treatment - Other

2

Description

Control group: Pregnant women in the placebo group will get a placebo capsule daily for one month, which is similar in appearance to a probiotic capsule.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Elham Tooti

Street address

hezar jrib

City

Isfahan

Province

Isfahan

Postal code

4144444444

Phone

+98 31 3620 2086

Email

elentooty@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mehdi Nemat bakhsh

Street address

hezar jrib

City

Isfahan

Province

Isfahan

Postal code

4144444444

Phone

+98 31 3620 2086

Email

nematbakhsh@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Elham Tooti

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Infectious diseases

Street address

Shohadaye Soffe, Alzahra Hospital

City

Esfahan

Province

Isfahan

Postal code

4144444444

Phone

+98 31 3620 2086

Fax

Email

drelhamtooty.inf@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Elham Tooti

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Street address

Shohadaye Soffe, Alzahra Hospital

City

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Isfahan

Postal code

4144444444

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Fax**Email**

drelhamtooty.inf@gmail.com

Street address

Shohadaye Soffe, Alzahra Hospital

City

Esfahan

Province

Isfahan

Postal code

4144444444

Phone

+98 31 3620 2086

Fax**Email**

drelhamtooty.inf@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Considering ethical issues

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Elham Tooti

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Infectious diseases