

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Assessment of the therapeutic effects of probiotic yougurt in comparison with clindamycin in the treatment of bacterial vaginosis in patients in the third trimester of pregnancy referring to prenatal clinic of Imam hospital

Protocol summary

Summary

This study was performed to determine the efficacy of probiotic yoghurt and clindamycin in the treatment of bacterial vaginosis in pregnant women in the second and third trimester, referring to Imam Hospital. In this randomized clinical trial, 300 pregnant women in the second and third trimester, after diagnosis of bacterial vaginosis, were assigned to receive either probiotic yoghurt (100 gram twice a day for one week) or orally-administered clindamycin (300 mg twice a day for one week). The patients were visited after one week of therapy for recurrence of symptoms and recheck of vaginal PH and were followed until the end of pregnancy for symptom recurrence with phone call and pregnancy outcomes (preterm labor, PROM) were compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104136183N1**
Registration date: **2011-04-23, 1390/02/03**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-23, 1390/02/03

Registrant information

Name

Fateme Golshahi

Name of organization / entity

Tehran Univ of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 2690

Email address

golshahi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2009-08-10, 1388/05/19

Expected recruitment end date

2010-12-15, 1389/09/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the therapeutic effects of probiotic yougurt in comparison with clindamycin in the treatment of bacterial vaginosis in patients in the third trimester of pregnancy referring to prenatal clinic of Imam hospital

Public title

Comparative efficacy of probiotic yoghurt and clindamycin in the treatment of bacterial vaginosis in pregnant women in the third trimester

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women in second or third trimester of pregnancy who had bacterial vaginosis according to the presence of minimally three Amsel Criteria, willing to participate
Exclusion criteria: having a positive history of background disease, positive urine culture, having a positive history of preterm labor and premature rupture

of the membranes, other vaginal infections

Age

From **16 years** old to **44 years** old

Gender

Female

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Faculty of Medicine, Tehran University of Medical Sciences

Street address

Poorsina St, Keshavarz Blvd.

City

Tehran

Postal code**Approval date**

2009-06-27, 1388/04/06

Ethics committee reference number

841

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

Acute vaginitis

ICD-10 code

N76.0

ICD-10 code description

Acute vaginitis

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

Bacterial vaginosis

Timepoint

before and after intervention

Method of measurement

turnessel paper

Secondary outcomes**1****Description**

preterm labor

Timepoint

before 37 weeks gestational age

Method of measurement

diagnosis of gynecologist

2**Description**

preterm rupture of membranes

Timepoint

before 37 weeks of gestational age

Method of measurement

diagnosis of a gynecologist

3**Description**

update: June 30, 2011; Recurrence Rate

Timepoint

-

Method of measurement

-

4**Description**

Update June 30, 2011; PH Level

Timepoint

-

Method of measurement

-

Intervention groups**1****Description**

Intervention: probiotic yoghurt (100 gram twice a day for one week)

Category

Treatment - Other

2**Description**

Control: orally-administered clindamycin (300 mg twice a day for one week).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam hospital, Clinic of Prenatal

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faculty of Medicine, Tehran University of Medical Sciences

Full name of responsible person

Maryam Ojaghi

Street address

Poorsina St, Blvd Keshavarz

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Faculty of Medicine, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran Univ of medical sciences

Full name of responsible person

Fateme Golshahi

Position

Resident of Ob & Gyn

Other areas of specialty/work

Street address

Imam hospital, Dept of Gyn

City

Tehran

Postal code

Phone

+98 21 6695 2690

Fax

Email

golshahi@razi.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran Univ of Medical Sciences

Full name of responsible person

Sedighe Hantoushzadeh

Position

Associate professor of Gyn

Other areas of specialty/work

Street address

Dept of Gyn, Imam hospital

City

Tehran

Postal code

Phone

+98 21 6119 2365

Fax

Email

hantoushzadeh@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran Univ of Medical Sciences

Full name of responsible person

Fateme Golshahi

Position

Resident of Ob& Gyn

Other areas of specialty/work

Street address

Imam hospital, Dept of Gyn

City

Tehran

Postal code

Phone

Fax

Email

golshahi@razi.tums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code
empty

Data Dictionary
empty