Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 (pretem 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)

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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
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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