Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of probiotics yoghurt as a complementary method on treatment and recurrence of bacterial vaginosis: a randomized controlled trial

Protocol summary

Summary

The objectives of this randomized controlled trial are to evaluate effect of probiotics yoghurt as a complementary method on improving treatment effect of Metronidazol and preventing recurrence of bacterial vaginosis. It will be conducted on 140 married women aged 15-49 years referring to Alzahra hospital clinics in Tabriz who have bacterial vaginosis (diagnosed by ≥3 Amsel criteria and Nugent score ≥ 4-6 or over 7 with no considering Clue Cells) and are not infected to other vaginal infections. Eligible women will be allocated into two groups using the Block Randomization with block sizes four and six. The intervention group will take Metronidazole oral tablets and probiotic yogurt, while the control group will take Metronidazole oral tablets and yoghurt with no probiotics. Similar packaging will be used to conceal the allocation sequence. The yoghurt packs will be sequentially numbered based on allocation sequence by a person not involved in data collection and analyzing. The patients will be asked to use 100 gr yoghurt packs three times a day for 60 days and come back to the clinic 10± 2 and 90 and 180 ± 7 days after starting treatment for outcome assessment. Outcomes are microbiological cure as assessed by ≤1 Amsel criteria and Nugent score ≤4-6 and clinical cure as reported by patient and clinician at days 10±2 and 90 and 180. Data will be analyzed by Chi-square using SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206243706N13**
Registration date: **2012-07-14, 1391/04/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-07-14, 1391/04/24

Registrant information

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 2699

Email address

alizades@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz university of Medical Sciences & Infectious disease research center

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2012-12-20, 1391/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of probiotics yoghurt as a complementary method on treatment and recurrence of bacterial vaginosis: a randomized controlled trial

Public title

Effectiveness of probiotics yoghurt on treatment and recurrence of bacterial vaginosis

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: 1- Married, non pregnant, non lactatating women aged 49-15 years 2-diagnosis of bacterial vaginosis by Amsel and Nugent Criteria). 3 - no abnormal vaginal bleeding. 4 - no probable intervening situations with the test results (menstruation at time of smear, having sex during last 48 houres, use of douch during last 48 houres) 5 -giving informeed consent to participate the study and be able to present at the clinic during next 24 houres, once every 2 weeks for next 2 month (to get the yoghurts), and also after 3 months, and after 6 months for assessments. Exclusion criteria: 1 - use of antibiotics in last 2 weeks. 2 - use of vaginal drugs in last 30 days. 3 - suffering from HIV. 4 - suffering from heart disease and kidney failure. 5 - Having surgery on the colon. 6 – smoking. 7 - Starting to use IUD in the last month or deciding to Insert IUD in following 3 months. 8 - useing immunosuppressive drugs.
Age
From **15 years** old to **49 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences, Reaserch deputy
Street address
Golgasht
City
Tabriz
Postal code
Approval date
2012-07-02, 1391/04/12
Ethics committee reference number
9156

Health conditions studied

1

Description of health condition studied
Bacterial Vaginosis
ICD-10 code
N76
ICD-10 code description
other inflammation of vagina and vulva

Primary outcomes

1

Description
Microbiological cure
Timepoint
10+-2 days after starting treatment
Method of measurement
Microbiologocal cure as assessed by Amsel criteria and Nugent score

2

Description
Recurrence of bacterial vaginosis
Timepoint
90 and 180 +- 7 days after starting treatment
Method of measurement
Amsel criteria and Nugent score

Secondary outcomes

1

Description
Clinical cure
Timepoint
10 +- 3 days and 90 and 180 +-7 days after starting treatment
Method of measurement
Patient and clinician reports

Intervention groups

1

Description
Intervention group(metronidazol tablet + probiotic yogurt) at first 7 days metronidazol(500 mg Twice a day) then probiotic yogurtdaily for 2 month.
Category
Treatment - Drugs

2

Description
Control group(metronidazol tablet + Pasteurized

yogurt)at first 7 days metronidazol(500 mg Twice a day) then Pasteurized yogurt daily for 2 month.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital clinics in Tabriz

Full name of responsible person

somayeh ziyadi

Street address

Artesh street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Infectious disease research center

Full name of responsible person

DR.Behrooz Nagili

Street address

Azadi Avenue,Sina educational and treatment center

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Infectious disease research center

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

Nursing & Midwifery faculty

Full name of responsible person

Somayeh Ziyadi

Position

MSc student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences, Nursing & Midwifery faculty

Full name of responsible person

Dr.Sakineh Mohamad alizade Charandabi

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PhD in reproductive Health,Assistant professor

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Person responsible for updating data

Contact

Name of organization / entity

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Somayeh Ziyadi

Position

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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