Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Assessment the effectiveness of bacterial vaginosis screening program in routine perinatal care and its effect on decrease of preterm labour

Protocol summary

Summary

This clinical trial study was conducted on 474 pregnant women at gestational stage between (2007) and (2008) years.the participants were randomly divided into two groups (intervention group and control group). Screening was performed in intervention group with amsel's criteria (3 of 4 needed for diagnosis). Positive cases were given cream clindamycin 2%for one week; then the outcome of the delivery was assessed in both groups. the data were analysed by spss 11 using descriptive statistics.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204219525N1**
Registration date: **2012-06-06, 1391/03/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-06-06, 1391/03/17

Registrant information

Name
Mehrnaz Mashoufi
Name of organization / entity
Ardabil University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Sciences

Expected recruitment start date

2007-03-21, 1386/01/01

Expected recruitment end date

2009-03-19, 1387/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the effectiveness of bacterial vaginosis screening program in routine perinatal care and its effect on decrease of preterm labour

Public title

Assessment the effectiveness of bacterial vaginosis screening program in routine perinatal care and its effect on decrease of preterm labour

Purpose

Screening

Inclusion/Exclusion criteria

Inclusion criteria: age between 18-35 years old; gestational age between 8-24 weeks and obtained writing consent.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **474**

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
medical ethics committee name
Street address
ardabil university of medical science, adrabil, Iran
City
ardabil
Postal code
Approval date
2007-02-04, 1385/11/15
Ethics committee reference number
904/6

Health conditions studied

1

Description of health condition studied
bacterial vaginosis
ICD-10 code
O23.5
ICD-10 code description
infections of the genital tract in pregnancy

Primary outcomes

1

Description
preterm delivery
Timepoint
termination of pregnancy
Method of measurement
date entry of delivery

Secondary outcomes

1

Description
preterm delivery
Timepoint
termination of pregnancy
Method of measurement
date entry of pregnancy

Intervention groups

1

Description
Intervention group was provied sample vaginal discharge then based on Amsel,s criteria(3 of 4 needed for diagnosis) confirmed bacterial vaginosis. positive cases were given cream clindamycin 2% for one week and were made follow up for two week after treatment.then, the outcome of the delivery was assessted in the group.
Category
Prevention

2

Description
Control group recived routin care pregnancy without screening for bacterial vaginosis.then the outcome of the delivery was assessted in the group.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shal medical health center
Full name of responsible person
Street address
khalkhal- kulur- Shal- Shal medical health center
City
khalkhal

2

Recruitment center
Name of recruitment center
No.1 medical health center
Full name of responsible person
Street address
No.1 medical health center, khalkhal
City
khalkhal

3

Recruitment center
Name of recruitment center
Kulur medical health center
Full name of responsible person
Street address
Kulur medical health center, Kulur, KhalKhal
City
Kulur, KhalKhal

4

Recruitment center
Name of recruitment center
Barandagh medical health center
Full name of responsible person
Street address
Barandagh medical health center- Barandagh- Khalkhal
City
Khalkhal

5

Recruitment center
Name of recruitment center
Beiragh medical health center
Full name of responsible person
Street address
Beiragh medical health center- Barandagh- Khalkhal
City
Khalkhal

6

Recruitment center
Name of recruitment center
Hashtjin medical center
Full name of responsible person
Street address
Hashtjin medical center, Hashtjin, khalkhal
City
Khalkhal

7

Recruitment center
Name of recruitment center
No.2 medical health center
Full name of responsible person
Street address
No.2 medical health center- Khalkhal
City
Khalkhal

8

Recruitment center
Name of recruitment center
Lerd medical health center
Full name of responsible person
Street address
Lerd medical health center- Khalkhal
City
Khalkhal

9

Recruitment center
Name of recruitment center
No. 3 medical health center
Full name of responsible person
Street address
No. 3 medical health center- Khalkhal
City
Khalkhal

10

Recruitment center
Name of recruitment center
Khojin medical health center
Full name of responsible person
Street address
Khojin medical health center- Khalkhal
City
Khalkhal

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil university of medical science
Full name of responsible person
Dr.Hadi Piri Doghahe
Street address
research deputy-Ardabil university of medical science-Ardabil
City
Ardabil
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ardabil university of medical science
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
Ardabil University of Medical Sciences
Full name of responsible person
Mehrnaz Mashoufi
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MSc/lecturer
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Person responsible for scientific inquiries

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Person responsible for updating data

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m.mashoufi@arums.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