

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

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

#### Protocol summary

Ardabil University of Medical Sciences

#### 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.

#### 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

#### General information

#### Scientific title

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

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT201204219525N1**

Registration date: **2012-06-06, 1391/03/17**

Registration timing: **retrospective**

#### Public title

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

Last update:

Update count: **0**

#### Registration date

2012-06-06, 1391/03/17

#### Purpose

Screening

#### Inclusion/Exclusion criteria

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

#### Registrant information

#### Name

Mehrnaz Mashoufi

#### Name of organization / entity

Ardabil University of Medical Sciences

#### Country

Iran (Islamic Republic of)

#### Phone

+98 45 1551 0052

#### Email address

m.mashoufi@arums.ac.ir

#### 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

#### Recruitment status

**Recruitment complete**

#### Funding source

## 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 provided 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 weeks after treatment. then, the outcome of the delivery was assessed in the group.

#### Category

Prevention

### 2

#### Description

Control group received routine care pregnancy without screening for bacterial vaginosis. then the outcome of the delivery was assessed 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

**Position**

MSc/lecturer

**Other areas of specialty/work**

**Street address**

Faculty of health, Ardabil University of Medical  
Sciences, Ardabil

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**Phone**  
+98 45 1551 0052  
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**Email**  
m.mashoufi@arums.ac.ir  
**Web page address**

## Person responsible for scientific inquiries

### Contact

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Ardabil University of Medical Sciences  
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Mehrnaz Mashoufi  
**Position**  
MS.c  
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Faculty of health, Ardabil University of Medical Sciences, Ardabil  
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**Fax**  
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m.mashoufi@arums.ac.ir  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Ardabil University of Medical Sciences  
**Full name of responsible person**  
Mehrnaz Mashoufi  
**Position**  
lecturer/MS.c  
**Other areas of specialty/work**  
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**Fax**  
**Email**  
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*