Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Comparison of vaginal misoprostol and intra cervical foleycatheter for cervical ripening of postdate primigravid women

Protocol summary

Study aim
Comparing cervical foley catheter and vaginal misoprostol in simplification of labor delivery

Design
This study is a randomized clinical trial which was conducted in the delivery and women hospital of Bandar-Abbas in 2016-2017. In this study 120 randomized postdate primigravid women between 18-35 yeares old who suffered from vaginal bleeding, abnormal fetal heartbeat, natural disease that needed to terminate the pregnancy season, misoprostol susceptibility and weren't utrine scar were selected. They were randomly divided into two groups of 60. In one group cervical foley catheter and in another one vaginal misoprostol 25 microgram was used.

Settings and conduct
This study is a randomized clinical trial which was conducted in the delivery and women hospital of Bandar-Abbas in 2016-2017. In this study 120 randomized postdate primigravid women between 18-35 yeares old who suffered from vaginal bleeding, abnormal fetal heartbeat, natural disease that needed to terminate the pregnancy season, misoprostol susceptibility and weren't utrine scar were selected. They were randomly divided into two groups of 60. In one group cervical foley catheter and in another one vaginal misoprostol 25 microgram was used. In terms of delivery progress need of oxytocin, Apgar score, delivery time, NICU requirement, meconium- stained amniotic fluid were examined. T

Participants/Inclusion and exclusion criteria
In this study 120 randomized postdate primigravid women between 18-35 yeares old who suffered from vaginal bleeding, abnormal fetal heartbeat, natural disease that needed to terminate the pregnancy season, misoprostol susceptibility and weren't utrine scar were selected.

Intervention groups
In one group cervical foley catheter and in another one vaginal misoprostol 25 microgram was used.

Main outcome variables
Time of normal vaginal delivery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181218042033N4**
Registration date: **2020-04-19, 1399/01/31**
Registration timing: **retrospective**

Last update: **2020-04-19, 1399/01/31**
Update count: **0**

Registration date
2020-04-19, 1399/01/31

Registrant information

Name
Nazanin Abdi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 76 3333 3280

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-08-15, 1396/05/24

Expected recruitment end date
2018-03-18, 1396/12/27

Actual recruitment start date
2017-08-15, 1396/05/24

Actual recruitment end date

2018-03-18, 1396/12/27

Trial completion date

2018-03-18, 1396/12/27

Scientific title

Comparison of vaginal misoprostol and intra cervical foleycatheter for cervical ripening of postdate primigravid women

Public title

Comparison of vaginal misoprostol and intra cervical foleycatheter for cervical ripening

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Primigravid women 18-35 yeares old Vaginal bleeding Abnormal fetal heartbeat Natural disease that needed to terminate the pregnancy season

Exclusion criteria:

Misoprostol susceptibility Uterine scar

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: use block; Random unit: Individual; Randomization tool: Statistical software Minitab; Sequence Building: Using randomized 4 in 4 blocks; Hiding method: Use similar bottles

Blinding (investigator's opinion)

Single blinded

Blinding description

Our colleague in this study in hospital delivered formulations to the participants of the study according to the randomized block table.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Homozgan University of medical sciences

Street address

Hormozgan University Of Medical Sciences, Chamran Blvd, Bandar abbas

City

Shiraz

Province

Fars

Postal code

7916839319

Approval date

2017-08-15, 1396/05/24

Ethics committee reference number

IR.HUMS.REC.1396.85

Health conditions studied

1

Description of health condition studied

Spontaneous delivery

ICD-10 code

O80.0

ICD-10 code description

Encounter for full-term uncomplicated delivery

Primary outcomes

1

Description

Cervical dilatation

Timepoint

Every 6 hours

Method of measurement

Vaginal examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: vaginal misoprostol 25 microgram

Category

Treatment - Drugs

2

Description

Intervention group: cervical foley catheter

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Hormozgan University of Medical Sciences

Full name of responsible person
Naznin Abdi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Bandare-abbas University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
Foroogh Pakbaz

Position
Resedient

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
IPD: Information and research data Ethic form: Complete the Ethic form by the patient
When the data will become available and for how long
IPD: 2018 Ethic form: 2018
To whom data/document is available
IPD: Researcher & Patient Ethic form: Patient
Under which criteria data/document could be used
IPD: Ethic form: Awareness of test results
From where data/document is obtainable
IPD: OB & Gyn ward Hormozgan university of medical sciences Ethic form: OB & Gyn ward Hormozgan university of medical sciences
What processes are involved for a request to access data/document
IPD: Vice chancellery Ethic form: Vice chancellery
Comments