

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Oct 2023

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)

Phone

+98 76 3333 3280

Email address

abdinazanin834@gmail.com

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 foley catheter for cervical ripening of postdate primigravid women

Public title
Comparison of vaginal misoprostol and intra cervical foley catheter 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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Hormozgan University Of Medical Sciences, Chamran Blvd, Bandar abbas

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Abdolazim Nejati Zadeh

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azimnejate@yahoo.com

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 scientific inquiries

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Position

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Person responsible for updating data

Contact

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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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