Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the Effect of Vaginal misoprostol with Oxytocin for the management of second trimester pregnancy terminations with IUFD in khalij fars hospital in Bandar Abbas in 2018.

Protocol summary

Study aim

The purpose of this study was to Comparison of the Effect of Vaginal misoprostol with Oxytocin for the management of second trimester pregnancy terminations with IUFD in khalij fars hospital in Bandar Abbas in 2018.

Design

They were randomly divided into two groups of 53 people. One of the groups was treated with 400 micrograms vaginal misoprostol every 6 hours for up to 48 hours and the other group was treated with high dose oxytocin 50 units in 500 cc ringer (up to a maximum dose of 300 units). In the event of failure of the treatment of the first line, the method of treatment was transferred to the groups and in case of failure of the second line (failure to pass the gestational period) the patient became a candidate for hysterotomy.

Settings and conduct

The present study is a randomized clinical trial. The population of this study was pregnant women in the second trimester of IUFD who referred to the khalij fars hospital during the year 2018.

Participants/Inclusion and exclusion criteria

Inclusion criteria were the pregnant women with 18 to 40 years of age confirmed by IUFD with gestational age of 15 to 26 weeks and exclusion criteria were multiparity more than 6, coagulopathy, multifetal pregnancy, any obstacle to induction of labor (e.g. maternal heart disease, clinical chorioamnionitis, vasa previa, placenta previa, invasive cervical carcinoma, myoma surgery or any surgery that has cut the uterine), having one or more caesarean section, and history of any uterine incision (myomectomy and etc.)

Intervention groups

One of the groups was treated with 400 micrograms vaginal misoprostol every 6 hours for up to 48 hours and the other group was treated with high dose oxytocin 50 units in 500 cc ringer (up to a maximum dose of 300 units). hysterotomy.

Main outcome variables

compare the effect of oxytocin with misoprostol on labor induction in the second trimester IUFDs.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181218042033N2**
Registration date: **2020-02-24, 1398/12/05**
Registration timing: **retrospective**

Last update: **2020-02-24, 1398/12/05**
Update count: **0**

Registration date

2020-02-24, 1398/12/05

Registrant information

Name

Nazanin Abdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3333 3280

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-18, 1397/12/27

Expected recruitment end date

2019-07-11, 1398/04/20

Actual recruitment start date
2019-03-18, 1397/12/27
Actual recruitment end date
2019-07-11, 1398/04/20
Trial completion date
2019-07-11, 1398/04/20

Scientific title
Comparison of the Effect of Vaginal misoprostol with Oxytocin for the management of second trimester pregnancy terminations with IUFD in khalij fars hospital in Bandar Abbas in 2018.

Public title
Comparison of the Effect of Vaginal misoprostol with Oxytocin for the management pregnancy terminations with IUFD
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women with 18 to 40 years of age confirmed by IUFD gestational age of 15 to 26 weeks
Exclusion criteria:
Multiparty more than 6 Coagulopathy Multi fetal pregnancy Any obstacle to induction of labor (e.g. maternal heart disease, clinical chorioamnionitis, vasa previa, placenta previa, invasive cervical carcinoma, myoma surgery or any surgery that has cut the uterine) Having one or more caesarean section History of any uterine incision (myomectomy and etc.).
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
2
Groups that have been masked

- Participant

Sample size
Target sample size: **106**
Actual sample size reached: **106**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple, block randomization
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants are no longer aware of the misoprostol or oxytosin recipes.
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
Bandar Abbas
Province
Hormozgan
Postal code
7916839319
Approval date
2019-03-17, 1397/12/26
Ethics committee reference number
IR.HUMS.198.001

Health conditions studied

1

Description of health condition studied
Intrauterine fetal death
ICD-10 code
O04
ICD-10 code description
Complications following (induced) termination of pregnancy

Primary outcomes

1

Description
Induction- to-delivery interval time
Timepoint
6-48 hours after misoprostol and oxytocin administration
Method of measurement
clock

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Vaginal misoprostol: 400 µg every 6 hours up to 48 hours
Category
Treatment - Drugs

2

Description

Control group: Oxytocin at a dose of 50 units of oxytocin at 500 cc Ringer (up to a maximum dose of 300 units)

Category

Treatment - Drugs

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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abdinazanin834@gmail.com

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

Atena Gisooee

Position

Resedient

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Latest degree

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Person responsible for updating data

Contact

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

Full name of responsible person
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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
Undecided - It is not yet known if there will be a plan to make this available

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