

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)

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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.).

AgeFrom **18 years** old to **40 years** old**Gender**

Female

Phase

2

Groups that have been masked

- Participant

Sample sizeTarget 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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bandare-abbas University of Medical Sciences
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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
Atena Gisooee
Position
Resedient
Latest degree
Specialist
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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

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