Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

A comparative study of vaginal misoprostol and intravenous oxytocin for induction of labor in women with second trimester pregnancy

Protocol summary

Summary

Second trimester labor induction is a major problem in obstetrics.To compare the effectiveness of vaginal misoprostol and intravenous oxytocin in induction of labor,100 women 12-24 weeks of gestation will participate in a randomised controlled way. The inclusion criteria consis of mothers with Intra uterine fetal death; fetal anomaly; Premature rupture of membrane; maternal complications and parity below 6. Mothers with multigestations; chorioamnionits; prostaglandin contraindication and sufficient uterine contraction will be excluded from the study. one of two groups will get 200 micro gram vaginal tablet misoprostol and repeat after 12 hours if necessary. Another group of patients will receive 50 units of oxytocin in 500 ml of dextrose- saline infusion over 3 hours, one hour of no oxytocin, followed by a 100 unit in 500 ml solution over 3 hours, another of rest , and a 150 units in 500 ml over 3 hours , the oxytocin will increased to a final concentration of 300 units in 500 ml. In either treatment arm the assigned medication will be continued until either maximum dose will administer or delivery will occurr, whichever come first. The two groups will compare for induction to delivery intervals and their safety during inductions. The success rate In misoprostol group and in second group (after 24 hours) will be assessed and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307159568N5**
Registration date: **2013-09-20, 1392/06/29**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-09-20, 1392/06/29

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Hormozgan University Medical of Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-01-21, 1392/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of vaginal misoprostol and intravenous oxytocin for induction of labor in women with second trimester pregnancy

Public title

Comparison of 2 different methods in Second trimester labor induction

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Intra uterine fetal death; fetal anomaly; PROM; maternal indications; Parity<5; previous cesarean section, Exclusion criteria: multi pregnancy; prostaglandin contraindication; uterine contraction; mothers dissatisfaction; more than 2 cesarean sections; chorioamnionits; placenta previa

Age
From **20 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Bandar Abas University of Medical Sciences

Street address
Bandar Aabas, Medical University

City
Bandar Abas

Postal code

Approval date
2004-09-22, 1383/07/01

Ethics committee reference number
83/84/32

Health conditions studied

1

Description of health condition studied
pregnancy

ICD-10 code
O00-O08

ICD-10 code description
Pregnancy with abortive outcome

Primary outcomes

1

Description
induction- to-delivery interval time

Timepoint
24 hours after misoprostol and oxytocin administration

Method of measurement
clock

Secondary outcomes

1

Description
Induction complications

Timepoint
During inductoion procedurs

Method of measurement
Observation and phisical exam

Intervention groups

1

Description
comparison of induction of labor in misoprostol & oxytocin groups. one of two groups will get 200 micro gram vaginal tablet misoprostol and repeat after 12 hours if necessary.

Category
Treatment - Drugs

2

Description
Another group of patients will receive 50 units of oxytocin in 500 ml of dextrose- saline infusion over 3 hours, one hour of no oxytocin, followed by a 100 unit in 500 ml solution over 3 hours, another of rest , and a 150 units in 500 ml over 3 hours , the oxytocin will increased to a final concentration of 300 units in 500 ml.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariaty Hospital. Bandar Abas

Full name of responsible person
Dr. Zhila Abedi Asl

Street address

City
Bandar Abas

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hormozgan University of Medical Sciences
Full name of responsible person
Dr. Abedi
Street address
Hormozgan-Bandar Abas . University of Medical Sciences
City
Bandar Abas
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hormozgan University of Medical Sciences
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
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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