Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

The efficacy of misoprostol and oxytocin for induction of labor

Protocol summary

Summary

This study will be conducted to investigate the effect of using sublingual Misoprostol and Oxytocin to induce labor on fetal electrocardiogram. In this study, pregnant women with a gestational age of 41 weeks or higher will be referred to the Midwifery Clinic meeting. Estimated sample size is 80 patients, who will be randomly in two groups; 40 cases will receive oxytocin and the other 40 receive misoprostol. First group will receive, 50 µg sublingual misoprostol (a quarter of tablet), every 4 hours up to 4 doses; the other group, receive oxytocin infusion rate of 2 mIU/min and will be increase by 2 mIU/min in every 15 minutes. Each group will be given the placebo drug of the other group. Inclusion criteria are: mothers desire to have vaginal delivery, gestational age of 41 weeks and above, having Bishop score below 5, normal non-stress test (NST) at birth, normal oxytocin challenge test (OCT), lack of uterine contractions. Exclusion criteria included: contraindication of misoprostol or oxytocin, fetal macrosomia, polyhydramnios, placenta previa or abruption, meconial, vaginal bleeding, intrauterine growth restriction, non-cephalic presentation, and narrow pelvis. Exclusion criteria are: contraindication of misoprostol or oxytocin, fetal macrosomia, polyhydramnios, placenta previa or abruption, meconial, vaginal bleeding, intrauterine growth restriction, non-cephalic presentation, and narrow pelvis. Then need for cesarean section and fetal heart rate changes will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122425648N2**
Registration date: **2016-02-21, 1394/12/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-02-21, 1394/12/02

Registrant information

Name
Masoumeh Mirteimori
Name of organization / entity
Mashhad University of Medical Sciemces
Country
Iran (Islamic Republic of)
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+98 915 113 0199
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rahmanish3@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-02-01, 1394/11/12

Expected recruitment end date

2016-05-01, 1395/02/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of misoprostol and oxytocin for induction of labor

Public title

Comparison the efficacy of misoprostol and oxytocin for induction of labor on fetal cardiotocogram in pregnancies with GA >= 41w

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria are: mothers desire to have vaginal

delivery, gestational age of 41 weeks and above, having Bishop score below 5, normal non-stress test (NST) at birth, normal oxytocin challenge test (OCT), lack of uterine contractions. Exclusion criteria included: contraindication of misoprostol or oxytocin, fetal macrosomia, polyhydramnios, placenta previa or abruption, meconial, vaginal bleeding, intrauterine growth restriction, non-cephalic presentation, and narrow pelvis. Exclusion criteria are: contraindication of misoprostol or oxytocin, fetal macrosomia, polyhydramnios, placenta previa or abruption, meconial, vaginal bleeding, intrauterine growth restriction, non-cephalic presentation, and narrow pelvis. Then need for cesarean section and fetal heart rate changes will be compared between two groups.

Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
none of the residents, midwives or attending gynecologists, will not aware of the information of groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Qoreishi Building, Daneshgah Street, Mashhad University of Medical Sciences, Mashhad, Iran
City
Mashhad
Postal code
1234567
Approval date
2013-08-20, 1392/05/29
Ethics committee reference number
IR.mums.REC.1392.911259162

Health conditions studied

1

Description of health condition studied
Prolonged pregnancy
ICD-10 code
O48
ICD-10 code description
Prolonged pregnancy

Primary outcomes

1

Description
Fetal heart beat changes
Timepoint
Every Half an hour
Method of measurement
Non-stress test

2

Description
need to perform cesarean section
Timepoint
Every half hour
Method of measurement
Clinical

Secondary outcomes

1

Description
APGAR
Timepoint
First and Fifth minutes
Method of measurement
Clinical

Intervention groups

1

Description
Intervention 1: 50 µg sublingual misoprostol (a quarter of tablet) will be administered, every 4 hours up to 4 doses and placebo
Category
Treatment - Drugs

2

Description
Intervention 2: oxytocin infusion will be administered 2 mIU/min infusion and increase by 2 mIU/min in every 15 minutes and placebo

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Omolbanin Hospital
Full name of responsible person
Masoumeh Mirteimouri
Street address
Ayatollah Behjat Avenue, Mashhad, Iran
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Mashhad University of Medical Sciences
Full name of responsible person
Masoumeh Mirteimouri
Street address
Qoreishi Building, Daneshgah Street, Vice Chancellor for Research of Mashhad University of Medical Sciences, Mashhad, Iran
City
Mashhad
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research of Mashhad 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
Mashhad University of Medical Sciences
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Person responsible for updating data

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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