

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 Sciences

Country

Iran (Islamic Republic of)

Phone

+98 915 113 0199

Email address

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 \geq 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 centers1**Recruitment center****Name of recruitment center**

Omolbanin Hospital

Full name of responsible person

Masoumeh Mirteimouri

Street address

Ayatollah Behjat Avenue, Mashhad, Iran

City

Mashhad

Sponsors / Funding sources1**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

Full name of responsible person

Masoumeh Mirteimouri

Position

Gynecologist/ Assistant professor

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Web page address

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