Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison between misoprostol and oxytocine in cervical ripening for labour induction: a randomized clinical trial

Protocol summary

Summary

1-Objectives: To compare the effect of misopristol and oxytocin in the preparation of the cervix in the induction of labour 2-Design: Randomized, clinical trial, not blinded. 3-How to do: After explaining about labour induction procedures and prepare a written testimonial cervical consciously from the patient and his wife will be getting. Women who enter the entry criteria to fill will be plan . The embryos before the induction of childbirth rate is measured and recorded. Referring to random women in the 95-members will receive oxytocin or misopristol soon as a person to the extent of the contraction phase, optimal heart rate achieved the embryo will be evaluated. In cases of tachysystole (contraction or more over the course of 10 minutes) and hipertone/hypersystole of the uterus (uterine contraction with a duration of over 2 minutes) and in the absence of fetal heart rate changes, the usual way to treat these issues will. In the case of hiperstimulation syndrome or fetal hypoxia, disconnected and induction will be performing a cesarean section. 4- Participants : Entry criteria : Medical indication for the induction of delivery; Single twin pregnancies; Gestational age more than 36 weeks; Vertex presentation ;The normal heart rate of embryos .The exit criteria: The embryo-pelvic dystocia; An estimated weight of over 4000 grams or evidence of a lack of fitness cephalopelvic ; Abnormal vaginal bleeding or any placenta previa; The number of pregnancy over 4; Fetal malformation; Previous uterine scar; Any situation that does not cause vaginal delivery indication, Any contraindication use of misopristol ; Severe polyhydramnios . 5- Interventions: For women who receive misopristol, 50 mcg of medication in posterior vaginal fornix will be placed. The dose every 4 hours to 25 mcg can be repeated up to a pattern of at least 3 contraction in 10 minutes get. The maximum dose of 200 mcg. If this is the contractile pattern up to 4 hours after injection of the seventh dose drug is created, it will be deemed a failure of induction of labour. After acquiring the contractile pattern will not be prescribing other ideal misopristol. For women, group 2 mU/min drug oxytocin for intravenous infusion will be used in intervals of 30 minutes 2 times the amount of the drug, as long as proper contractile pattern. The dose up to maximum 20 mU/min infusion is increased and the limit will be preserved. If desired the contractile pattern up to 15 mU did, failure of induction of delivery will be considered. Even after the acquisition of optimum pattern of contractile administered oxytocin will continue. 6-The main outcome variables: Bishop Index

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012103011324N1**
Registration date: **2013-01-13, 1391/10/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-01-13, 1391/10/24

Registrant information

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Recruitment status

Recruitment complete

Funding source

Ahwaz Jundishapur University of Medical Science, Vice

Chancellor for Research and Technology

Expected recruitment start date
2013-01-20, 1391/11/01
Expected recruitment end date
2013-02-18, 1391/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison between misoprostol and oxytocine in cervical ripening for labour induction: a randomized clinical trial

Public title
Comparison between misoprostol and oxytocine in cervical ripening for labour induction: a randomized clinical trial
Purpose
Treatment
Inclusion/Exclusion criteria
Entry criteria : Medical indication for the induction of delivery; Single twin pregnancies; Gestational age more than 36 weeks; Vertex presentation ;The normal heart rate of embryos .The exit criteria: The embryo-pelvic dystocia; An estimated weight of over 4000 grams or evidence of a lack of fitness cephalopelvic ; Abnormal vaginal bleeding or any placenta previa; The number of pregnancy over 4; Fetal malformation; Previous uterine scar; Any situation that does not cause vaginal delivery indication, Any contraindication use of misopristol ; Severe polyhydramnios
Age
No age limit
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **190**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ahwaz Ethic Committee of Jundishapur University of Medical Sciences
Street address
Ahwaz Jundishapur University of Medical Sciences , Esfand avenue , Golestan bulvard
City
Ahwaz
Postal code
61357-15794
Approval date
2012-06-09, 1391/03/20
Ethics committee reference number
493

Health conditions studied

1

Description of health condition studied
Failed medical induction of labour
ICD-10 code
O61.0
ICD-10 code description
Failed induction (of labour) by:•oxytocin•prostaglandins

Primary outcomes

1

Description
Bishop index
Timepoint
Baseline and every 30 minutes during the intervention and at the end of the intervention
Method of measurement
The questionnaire

Secondary outcomes

1

Description
Infantile complication
Timepoint
Baseline and every 30 minutes during the intervention and at the end of the intervention
Method of measurement
Apgar score

Intervention groups

1

Description
For women who receive misopristol, 50 mcg of

medication in posterior fornix of vagina will be placed. The dose every 4 hours to 25 mcg can be repeated up to a pattern of at least 3 contraction in 10 minutes get. The maximum dose of 200 mcg. If this is the contractile pattern up to 4 hours after injection of the seventh dose drug is created, it will be deemed a failure of induction of labour. After acquiring the contractile pattern will not be prescribing other ideal misopristol

Category

Treatment - Drugs

2

Description

For oxytocin group 2 mU/min of the drug for intravenous infusion will be used in intervals of 30 minutes 2 times the amount of the drug, as long as proper contractile pattern. The dose up to maximum 20 mU/min infusion is increased and the limit will be preserved. If desired the contractile pattern up to 15 mU did, failure of induction of delivery will be considered. Even after the acquisition of optimum pattern of contractile administered oxytocin will continue. As soon as a person to the extent of the contraction phase, optimal heart rate achieved the embryo will be evaluated. Amniotomy will be conducted when the Bishop score over 7 and Bishop cervix over 6 cm. In cases of tachysystole (contraction or more over the course of 10 minutes) and hiprtone/hypersystole of the uterus (uterine contraction with a duration of over 2 minutes) and in the absence of fetal heart rate changes, the usual way to treat these issues will. In the case of hiprerstimulation syndrome or fetal hypoxia, disconnected and induction will be performing a cesarean section

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital

Full name of responsible person

Razie Mohamadjafari MD

Street address

Imam Khomeini Hospital , Azadegan avenue

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahwaz Jundishapur University of Medical Science, Vice Chancellor for Research and Technology

Full name of responsible person

Dr.Mostafa Feghhi

Street address

Vice Chancellor for Research and Technology , Ahwaz Jundishapur University of Medical Science, Esfand avenue , Golestan bulvard

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Ahwaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahwaz Jundishapur University of Medical Science, Vice Chancellor for Research and Technology

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

Ahwaz Jndishapur University of Medical Sciences

Full name of responsible person

Mehrnooh Namazi

Position

Assistant of Obstetrics and Gynecology

Other areas of specialty/work

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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