

# 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 misoprostol 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 misoprostol 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 misoprostol ; Severe polyhydramnios . 5- Interventions: For women who receive misoprostol, 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 misoprostol. 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

##### Name

Mehrnoosh Namazi

##### Name of organization / entity

Ahwaz Jundishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1333 8915

##### Email address

mohamadjafari-r@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahwaz Jundishapur University of Medical Science, Vice

**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 boulevard

**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 hiperstimulation 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 Fegghi

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

**City**

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

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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*