

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### A comparison between sublingual Misoprostol and intravenous Oxytocin for inducing labor in women at term

#### Protocol summary

##### Summary

Background: Promotion of normal vaginal delivery is effective on reducing cesarian section and then complications due to it. In this study efficacy of sublingual Misoprostol will examine for induction of labor at term in compare with Oxytocin infusion in mirza khoochakkhan in 2010-2011 Methods: Seventy term-pregnant women with unfavourable cervix were randomized to sublingual Misoprostol or intravenous Oxytocin groups by blockig method after getting informed written consent Sublingual Misoprostol group (group A,n=35) (Searle company) received 25 µg four hourly to maximum of 5 doses. Administration was continued until cervix was ready for amniotomy, spontaneous rupture of membranes, or starting active phase. Oxytocin intravenous infusion (group B,n=35)(Caspian company) 10 U/lit, was initiated at 1 mU/min and if necessary, stepped up by 1 mU/min every 15 minutes then continued at the same till delivery completed. Permanent monitoring was done in both groups and Contractures were controlled every 15 min for assessing need to increase medicine administration. Only in situation of ineffective contractures and after doing NST, an additional dose of Misoprostol was administered. Amniotomy was performed when active phase had been started (cervix dilatation => 3cm) and membrane was intact. Determination of latent phase duration and starting active phase was done by vaginal examination. Vital signs were recorded from starting contractures until one hour of placenta voiding. Promethazine (25 mg IM) for nausea and Pethidine (50 mg, IM) for pain were used if necessary. Conclusion: if sublingual Misoprostol is better than intravenous Oxytocin for induction of labor at term or not. specific targets: 1-comparing mean of latent phase between Misoprostol and oxytocin group 2- comparing mean of active phase between Misoprostol and oxytocin group 3-comparing mean of starting time of inducing labour till delivery between Misoprostol and oxytocin group 4-

comparing prevalence of uterous hypertonicity between Misoprostol and oxytocin group 5- comparing prevalence of meconium staining between Misoprostol and oxytocin group 6- comparing prevalence of decreasing FHR between Misoprostol and oxytocin group 7- comparing mean of Apgar score in first minute after delivery between Misoprostol and oxytocin group 8-comparing mean of Apgar score in fifth minute after delivery between Misoprostol and oxytocin group 9-comparing prevalence of caesarian section between Misoprostol and oxytocin group

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201205089636N1**  
Registration date: **2012-05-28, 1391/03/08**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-05-28, 1391/03/08

##### Registrant information

##### Name

Laleh Ghadirian

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

lghadirian@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

vice chancellor of research of Tehran University of

## Expected recruitment start date

2011-11-19, 1390/08/28

## Expected recruitment end date

2012-06-19, 1391/03/30

## Actual recruitment start date

empty

## Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

A comparison between sublingual Misoprostol and intravenous Oxytocin for inducing labor in women at term

## Public title

effect of sublingual Misoprostol in inducing labor

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria were gestational age 37 - 42 weeks, Bishop Score = < 4, Indication for labor induction, cephalic presentation, reactive NST. Exclusion criteria were Bishop score > 4), gestational age less than 37 and more than 42, non-vertex presentation, intrauterine demise, previous uterine surgery, oligo or polyhydramnios, intrauterine growth retardation, multiple pregnancy, clinical evidence of cardiopulmonary collapse, electrolyte abnormalities, severe pre-eclampsia/eclampsia, hepatitis, asthma, glaucoma and adrenal insufficiency ,

## Age

From **18 years** old to **45 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **70**

## 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

Ethics committee of Tehran University of medical sciences

##### Street address

5 th floor- qods avenue- keshavarz Blv

##### City

Tehran

##### Postal code

##### Approval date

2011-11-19, 1390/08/28

##### Ethics committee reference number

1470

## Health conditions studied

### 1

#### Description of health condition studied

Indication for terminating pregnancy with low Bishop score

#### ICD-10 code

P05-P08

#### ICD-10 code description

Disorders related to length of gestation and fetal growth

## Primary outcomes

### 1

#### Description

Indication for terminating pregnancy with unfavorable contractures and cervix

#### Timepoint

Every 15 minutes

#### Method of measurement

Physical examination

## Secondary outcomes

### 1

#### Description

Vaginal delivery vs caesarian section

#### Timepoint

At the end of delivery

#### Method of measurement

Patients medical record

## Intervention groups

### 1

#### Description

Intervention group: sublingual Misoprostol

#### Category

Treatment - Drugs

**2**

**Description**

Control group: intravenous Oxytocin

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Mirzakhoochakkhan Hospital

**Full name of responsible person**

**Street address**

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice-chancellor for research, Tehran University of Medical Sciences

**Full name of responsible person**

Dr Akbar Fotouhi

**Street address**

Keshavarz Blv, qods street, 5th floor

**City**

Tehran

**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, Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Laleh Ghadirian

**Position**

Preventive and Community Medicine Specialist

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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*