# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

31 May 2026

## A comparision of out patient oral and vaginal Isosorbide dinitrate in cervical ripening befor induction of labor in post term pregnancy with low bishop score

## Protocol summary

**Summary**

This randomized double-blind clinical trial compares the efficacy of outpatient vaginal and oral isosorbide dinitrate (ISDN) on cervical ripening before induction of labor. 150 nulliparous women are randomly assigned into three groups: vaginal ISDN (40 mg), oral ISDN (20 mg), control (no drug).The Bishop score is determined at the beginning of the study. After taking medication, the patients will be under observe for 4 hours and then discharged and advised to return 24 hours later for assessing Bishop score and induction of labor. If adequate contractions is not induced with max 40 mIU/min oxytocin,labor induction is stopped and the patient returns to prenatal unit waiting for second induction in the next day. With adequate contractions, induction to delivery time and method of pregnancy termination will be compared between groups. Statistical analysis is performed with the use of the SPSS software, version16. To compare quantitative data between the three groups with normal distribution, one way ANOVA and to compare pairs of groups (if significant) Post Hoc Tokey method is used. Chi square test is used to compare qualitative variables between the three groups. p≤0.05 considered to be significant r.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201108157334N1**
Registration date: **2012-10-08, 1391/07/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2012-10-08, 1391/07/17

**Registrant information**

**Name**
Mahsa Kaveh
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tehran university
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**Recruitment status**

**Recruitment complete**

**Funding source**

|Vice chancellor for research of Tehran University of Medical Sciences

**Expected recruitment start date**

2012-03-19, 1390/12/29

**Expected recruitment end date**

2013-03-19, 1391/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A comparision of out patient oral and vaginal Isosorbide dinitrate in cervical ripening befor induction of labor in post term pregnancy with low bishop score

**Public title**

Efficacy of Isosorbide dinitrate in cervical ripening

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: 1)Nulliparity 2)Gestational age>42

weeks 3)Bishop score<5 4)Singleton pregnancy 5)Cephalic presentation 6) filled Consent form. Exclusion criteria: 1)Premature rupture of membrane 2)Vaginal bleeding 3)Contraindication for ISDN 4)History of any uterian scar 5)Intolerance to ISDN 6)Any systemic disease 7)Laber pain 8)Oligohydramnios 9)IUGR 10)Non-reassuring FHR

**Age**
From **10 years** old to **50 years** old

**Gender**
Female

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **150**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Tehran University of Medical Sciences Ethics Committee

**Street address**
Tehran University of Medical Sciences, Enghelab st.

**City**
Tehran

**Postal code**

**Approval date**
2012-01-16, 1390/10/26

**Ethics committee reference number**
2014

## Health conditions studied

### 1

**Description of health condition studied**
Isosorbide dinitrate effect on cervical ripening

**ICD-10 code**
P08

**ICD-10 code description**
Disorders related to long gestation and high birth weight

## Primary outcomes

### 1

**Description**
Cervical ripening

**Timepoint**
24 hours

**Method of measurement**
Vaginal exam

## Secondary outcomes

### 1

**Description**
Time from full dilatation to delivery

**Timepoint**
Stage 2 of labor

**Method of measurement**
Minut

### 2

**Description**
Time from active phase to full dilation

**Timepoint**
Stage 1 of labor

**Method of measurement**
Minut

### 3

**Description**
from induction to active phase

**Timepoint**
active phase

**Method of measurement**
minut

## Intervention groups

### 1

**Description**
Samples of investigation are divided into three groups based on randomly numbers table., in one group isosorbide dinitrate 40 mg should be placed vaginaly in posterior fornix.The Bishop score is determined at the beginning of the study. After taking medication, the patients will be under observe for 4 hours and then discharged and advised to return 24 hours later for assessing Bishop score and induction of labor.THE induction starts with2.5mIU/min of 10 unit oxitocin in 1000 ml Ringer lactate and every fifteen minutes 2.5mIU/min will be added . With adequate contractions, induction to delivery time is measured. If adequate contractions is not induced with max 40 mIU/min oxytocin,labor induction is stopped and the patient returns to prenatal unit waiting for second induction in the next day .if bishop score with adequate contractions dont change after 12 hours, labor induction is stopped

and the patient returns to prenatal unit waiting for second induction in the next day Also, if headache is occures after administration of ISDN, patient should be given acetaminophen. .

**Category**

Treatment - Drugs

**2**

**Description**

Samples of investigation are divided into three groups based on randomly numbers table., in one group isosorbide dinitrate20 mg should be given oraly.The Bishop score is determined at the beginning of the study. After taking medication, the patients will be under observe for 4 hours and then discharged and advised to return 24 hours later for assessing Bishop score and induction of labor.THE induction starts with2.5mIU/min of 10 mg oxitocin in 1000 ml Ringer lactate and every fifteen minutes 2.5mIU/min will be added . With adequate contractions, induction to delivery time MEASURE. If adequate contractions is not induced with max 40 mIU/min oxytocin,labor induction is stopped and the patient returns to prenatal unit waiting for second induction in the next day .if bishop score with adequate contractions dont change after 12 hours, labor induction is stopped and the patient returns to prenatal unit waiting for second induction in the next day Also, if the headache is detect after administration of ISDN shuld given acetaminophen. .

**Category**

Treatment - Drugs

**3**

**Description**

Samples of investigation are divided into three groups based on randomly numbers tablethat one group is control.they dont take any drug.The Bishop score is determined at the beginning of the study.THE induction starts with2.5mIU/min of 10 mg oxitocin in 1000 ml Ringer lactate and every fifteen minutes 2.5mIU/min will be added . With adequate contractions, induction to delivery time is measured. If adequate contractions is not induced with max 40 mIU/min oxytocin,labor induction is stopped and the patient returns to prenatal unit waiting for second induction in the next day .if bishop score with adequate contractions dont change after 12 hours, labor induction is stopped and the patient returns to prenatal unit waiting for second induction in the next day.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Akbar Abadi hospital

**Full name of responsible person**

**Street address**

**City**

Tehran

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research of Tehran University of Medical Sciences

**Full name of responsible person**

Dr Ladan Haghighi

**Street address**

Akbar abadi hospital

**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 of 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**

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**Position**

Associated professor

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## Person responsible for scientific inquiries

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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*