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
Name of organization / entity
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

Dr Ladan Haghighi

Position

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Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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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