Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

A comparative study of the use of oxytocin (Iranian-made and foreign) in the induction of labor.

Protocol summary

Summary

There are many ways to induce labor. This study compared the therapeutic effect of oxytocin (Oxy Tocip made in Iran with the external type called oxytocin) in the induction of labor in the Term and post term pregnancy. In this study, 200 pregnant women with a live fetus and cephalic presentation and more than 37 weeks gestational age are examined by a specialist and they will be included if the Bishop score is less than 4 and there are no uterine contractions. Exclusion criteria are uterine contractions, bleeding, abnormal fetal presentation, multiple and irregular fetal heart rate. Participants are randomly divided into two groups. Oxytocin 10 units in 1000 cc of serum Ringer is started and will be added every 15 minutes to reach a maximum of 40 mu / min. The induction of cervical dilatation and effacement during the first 30 minutes of active labor and every 15 minutes during the second stage of labor is controlled to determine the progress of labor. The primary outcome of the Labor is mean time between induction and delivery time.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011275181N3**
Registration date: **2012-01-12, 1390/10/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-01-12, 1390/10/22

Registrant information

Name

Batool Rashidi

Name of organization / entity

Vali E Asr Reproductive Health Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 6693 9320

Email address

bhrashidi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Drug costs will be paid by the Caspian Company.

Expected recruitment start date

2011-04-09, 1390/01/20

Expected recruitment end date

2012-04-08, 1391/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the use of oxytocin (Iranian-made and foreign) in the induction of labor.

Public title

Comparing the Oxytocin made in Iran with Oxytocin from foreign country for induction of labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: one Fetal pregnancy; Cephalic presentation; intact amniotic membrane; Reactive NST; less than 3 uterus contraction per 10 minutes. Exclusion criteria: regular contraction (more than 6 contraction per hours); fetal death; Amniotomy contra indication; mother age less than 18 years; previous C/S; Multiparty (>3); Chorioamniotit; Asthma history; Multiple gestation;

Placenta previa; Non Cephalic presentation; Glucoma; Vaginal bleeding; sensitivity to Prostoglandin; irregular in fetal heart rate; contra indication of vaginal delivery.

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice Chancellor for Research,Tehran University of Medical Sciences

Street address
Bulding of Vice Chancellor for Research, Ghods St., Keshavarz Blvd.

City
Tehran

Postal code

Approval date
2009-12-20, 1388/09/29

Ethics committee reference number
9992

Health conditions studied

1

Description of health condition studied
Long labor

ICD-10 code
O63

ICD-10 code description
Long labour

Primary outcomes

1

Description
Cesarian Section

Timepoint
at the end of induction of labor

Method of measurement
C/S or vaginal delivery

Secondary outcomes

1

Description
Duration of labor induction

Timepoint
Since the beginning of induction to delivery time

Method of measurement
Based on time

2

Description
Duration of first labor period

Timepoint
begining of induction until delivery time

Method of measurement
based on hours

3

Description
During the second stage of labor

Timepoint
Onset of contractions to full cervical dilatation

Method of measurement
Based on time

4

Description
uterine hyper stimulation

Timepoint
Time of contraction is more than two minutes.

Method of measurement
Based on an specialist examination

Intervention groups

1

Description
The group 1 (oxytocin), First 10 units oxytocin spilled in 1000 cc of blood Ringer (2/5mu/min) Then four drops per minute infusion rate 2 / 5 is increased to the maximum mu / min 40 in. The same amount will continue. After a good start uterine contractions, vaginal examination will be done if the patient Prom every hour and in rupture of the amniotic soc every 2 hour and every half hour inuterine contractions. mother's vital signs will be

controlled before oxytocin induction and then each hour. If signs of fetal distress or uterine hyperstimulation appears, oxytocin is stopped. In an extreme case of improved The uterus stimulation and fetal distress, re-infusion with previous dose begins and continues with the same sequence. If 6 hours after induction does not change, the patient with pain induction is regarded as a failure of Bishop Score and Induction will be stopped But if you switch off the induction of cervical, induction continues. The rate of cervical dilatation and effacement during the induction phase of active labor and every 30 minutes every 15 minutes during the second stage of labor is controlled To determine the progress of labor.

Category

Treatment - Drugs

2

Description

The group 2 (oxytocip), First 10 units oxytocin spilled in 1000 cc of blood Ringer (2/5mu/min) Then four drops per minute infusion rate 2 / 5 is increased to the maximum mu / min 40 in. The same amount will continue. After a good start uterine contractions, vaginal examination will be done if the patient Prom every hour and in rupture of the amniotic soc every 2 hour and every half hour inuterine contractions. mother's vital signs will be controlled before oxytocin induction and then each hour. If signs of fetal distress or uterine hyperstimulation appears, oxytocin is stopped. In an extreme case of improved The uterus stimulation and fetal distress, re-infusion with previous dose begins and continues with the same sequence. If 6 hours after induction does not change, the patient with pain induction is regarded as a failure of Bishop Score and Induction will be stopped But if you switch off the induction of cervical, induction continues. The rate of cervical dilatation and effacement during the induction phase of active labor and every 30 minutes every 15 minutes during the second stage of labor is controlled To determine the progress of labor.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Labor unit of Vali-e-Asr Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Caspian Pharmaceutical Company

Full name of responsible person

Dr. Arghavani

Street address

No. 1, Fatemi Ave., Bisutun First Ave.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Caspian Pharmaceutical Company

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Vali-E-Asr Reproductive Health Research Center

Full name of responsible person

Rashidi Batool

Position

Associate Proffesor

Other areas of specialty/work

Street address

Imam Khomeini Hospital, Vali-Asr Hospital, Tehran University of Medical Sciences

City

Tehran

Postal code

Phone

+98 21 6658 1616

Fax

Email

bhrashidi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Haghollahi Fedyeh

Position

Other areas of specialty/work

Street address

City
Postal code
Phone
Fax
Email
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