

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison the effect of interrupted and continuous Oxytocin during active phase on duration of labor, maternal and neonatal outcomes in normal vaginal delivery labor

Protocol summary

Summary

Objectives: The aim of this study is to investigate the effect of early interrupting of Oxytocin compared to continuing of Oxytocin during the active phase of labor, cesarean risk during labor, maternal and neonatal outcomes; so we can increase the mother and infant safety and reach to hospital aims for Mother-Baby Friendly Hospital which is normal vaginal delivery with minimal intervention. **Design, Setting and conduct:** In a prospective randomized clinical trial, all patients who will randomize by blocks divide into two groups. The first group will receive Oxytocin which continue until delivery and in second group Oxytocin discontinued in initial of active phase. **Participants, inclusion and exclusion criteria:** All pregnant women with gestational age ≥ 34 weeks and vertex presentation and an indication for induction (gestational age less than 42 weeks, rupture of membranes - oligohydramnios, high blood pressure) enrolled in study. **Inclusion criteria** included singleton pregnancy, vertex presentation, estimated weight <4 kg, gestational age > 34 weeks without any contraindication for NVD. **Exclusion criteria** included any contraindication for normal vaginal delivery or administration of Oxytocin such as malpresentation, Placenta Previa, previous cesarean section cervix surgery, Twin or multiple pregnancy, uncertain fetal heart rate. **Intervention:** All women will receive 10 units of Oxytocin by infusion. Oxytocin initiated equal to 2mu/min and increased 2mu/min every 15 minutes up to mg 32mu/min or until contractions of uterine reach to 3-5 per 10 minutes. Oxytocin is maintained at a constant level at this time. After the beginning of the active phase (cervical dilatation 4 cm) then patients divided into 2 groups, in the first group Oxytocin continues until delivery and in the other group will discontinue at the beginning of the active phase. **Main outcome:** Patients undergoing vaginal exam to evaluate the progress of labor and fetal heart

rate and uterine contractions is controlled every 15 minutes . If in second group within 2 hours cervix dilatation do not progress or numbers of contractions reach to less than 3 contractions per 10 minutes, Oxytocin start again. Also, if there is Non-Reassuring Fetal Heart Rate Patterns in first group, Oxytocin will discontinue. Duration of the active phase, total duration of labor, amount of administrated Oxytocin intake, maternal complications (including uterus hyperstimulation which is 6 or more uterine contractions per 10 minutes), Non-Reassuring Fetal Heart Rate Patterns, abnormal postpartum hemorrhage and type of delivery (caesarean or normal) and its reason, neonatal outcomes including fifth minute Apgar score, and admission to NICU evaluate in both groups. The decision for cesarean delivery will make based on obstetrical indications includes decelerations and lack of progress and is same in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102211019N2**

Registration date: **2013-12-20, 1392/09/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-20, 1392/09/29

Registrant information

Name

Mojgan Rahmanian

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone
+98 23 1444 1022

Email address
rahmanian@sem-ums.ac.ir

Recruitment status
Recruitment complete

Funding source
Vice Chancellor for Research, Semnan University of Medical Sciences

Expected recruitment start date
2013-11-22, 1392/09/01

Expected recruitment end date
2014-05-21, 1393/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the effect of interrupted and continuous Oxytocin during active phase on duration of labor, maternal and neonatal outcomes in normal vaginal delivery labor

Public title
Effect of interrupted and continuous Oxytocin on duration of labor

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Singleton pregnancy; Vertex presentation; Estimated weight <4 kg; gestational age > 34 weeks; Absence of any contraindication for NVD.
Exclusion criteria: Any contraindication for normal vaginal delivery; Any contraindication for administration of Oxytocin such as Malpresentation, Placenta Previa; Previous cesarean section; Cervix surgery; Twin or multiple pregnancy; Uncertain fetal heart rate.

Age
No age limit

Gender
Female

Phase
3

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 Semnan University of Medical Sciences

Street address

Basidj Boulevard

City

Semnan

Postal code

Approval date

2013-10-07, 1392/07/15

Ethics committee reference number

92/352431

Health conditions studied

1

Description of health condition studied

Normal Vaginal Delivery

ICD-10 code

O80.0

ICD-10 code description

Spontaneous vertex delivery

Primary outcomes

1

Description

Active delivery phase

Timepoint

Every 15 minutes after intervention

Method of measurement

Clinical examination

Secondary outcomes

1

Description

Cervix dilatation; Fetal Heart Rate Patterns

Timepoint

2 hours after intervention

Method of measurement

Clinical examination

Intervention groups

1

Description

All patients in first group receive 10 units of oxytocin by infusion. Oxytocin initiated equal to 2mu/min and increased 2mu/min every 15 minutes up to mg 32mu/min or until contractions of uterine reach to 3-5 per 10 minutes. Oxytocin is maintained at a constant level at this time. After the beginning of the active phase (cervical dilatation 4 cm) oxytocin continues until delivery.

Category

Treatment - Other

2

Description

All women in second group will receive 10 units of oxytocin by infusion. Oxytocin initiated equal to 2mu/min and increased 2mu/min every 15 minutes up to mg 32mu/min or until contractions of uterine reach to 3-5 per 10 minutes. Oxytocin is maintained at a constant level at this time. After the beginning of the active phase (cervical dilatation 4 cm) then oxytocin will be stopped at the beginning of the active phase.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al Momenin Hospital

Full name of responsible person

Maryam Sina

Street address

Imam Hussein square

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Semnan University of Medical Sciences

Full name of responsible person

Raheb Ghorbani

Street address

Basidj Boulevard

City

Semnan

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, Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Maryam Sina

Position

Obstetrics and Gynecology resident

Other areas of specialty/work

Street address

Imam Hussein Square

City

Semnan

Postal code

Phone

+98 23 1446 3052

Fax

Email

maryam_6022@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mojgan Rahmadian

Position

Gynecologists

Other areas of specialty/work

Street address

Imam Hussein Sq.

City

Semnan

Postal code

3519734731

Phone

+98 23 1446 3052

Fax

Email

rahmadian@sem-ums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mehrdad Zahmatkesh

Position

Research expert

Other areas of specialty/work**Street address**

Basidj Boulevard, Kowsar Hospital

City

Semnan

Postal code**Phone**

+98 23 1443 7822

Fax**Email**

mehrdadzahmatkesh@sem-ums.ac.ir

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