Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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; Abscence 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

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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

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Other areas of specialty/work

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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