Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of the Effectiveness of Amniotomy with Early and Delayed Infusion of Oxytocin on Birth Experiences and Some Maternal and Neonatal Outcomes in Nulliparous Women with Prolonged Labor: A Randomized Controlled Trial

Protocol summary

Study aim

To Compare Effect of Amniotomy with Early and Delayed Infusion of Oxytocin in Nulliparous Women with Prolonged Labor on Labor Experience and Some Maternal and Neonatal Outcomes

Design

In this trial, 351 women will be equally allocated into three parallel groups receiving early or delayed oxytocine infusion, or routine intervention, using a stratified block randomization with block sizes of 3, 6 and 9.Consecutively numbered opaque sealed envelopes will be used for the allocation concealment.

Settings and conduct

In Al-Zahra and Taleghani teaching hospitals in Tabriz, eligible women will be allocated to one of the three study groups using stratified block randomization, after receiving informed written consent and will be continuously monitored until delivery and followed up until discharge.

Participants/Inclusion and exclusion criteria

Inclusion criteria: nulliparous women aged 18 years or more with singleton alive fetus at a gestational age of 37-41 weeks, cephalic presentation, normal cardiotocogram, and bishop score of 6 or more with cervical dilatation of 4-6 cm hospitalized for vaginal delivery and have dilatation progress of less than 1 cm/h for 3 h or dilatation arrest for 2 h along with weak uterine contractions (less than 3 contractions in 10 min), and intact amniotic sac or less than 30 min after its rupture. Exclusion criteria: history of any incisions on the uterus, abnormal pelvic dimensions, history of infertility, any genital infection interfering with vaginal delivery, estimated fetal weight of more than 4000 g, severe fetal anomalies interfering with vaginal delivery.

Intervention groups

Group 1- amniotomy and early infusion of oxytocin, Group 2 - amniotomy and delayed infusion of oxytocin, Group 3 - hospital routine intervention.

Main outcome variables

The interval between intervention initiation and vaginal delivery; Score of maternal satisfaction with labor process

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100414003706N32**
Registration date: **2018-11-22, 1397/09/01**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-22, 1397/09/01**
Update count: **0**

Registration date

2018-11-22, 1397/09/01

Registrant information

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-21, 1397/08/30

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Amniotomy with Early and Delayed Infusion of Oxytocin on Birth Experiences and Some Maternal and Neonatal Outcomes in Nulliparous Women with Prolonged Labor: A Randomized Controlled Trial

Public title

Comparison of Effect of Early and Delayed Oxytocin Infusion on Some Maternal and Neonatal Outcomes in Prolonged Labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Nulliparous women during labor with alive singleton fetus at gestational age of 37-41 weeks, Aged 18 years or more, Body mass index of 18.5-30 kg/m2, Cephalic presentation of the fetus, Bishop score of 6 or more with cervical dilatation of 4-6 cm, Prolonged labor: progress of cervical dilatation less than 1 cm/h for 3 h or dilatation arrest for 2 h, with weak uterine contractions (less than 3 contractions in 10 min), Intact amniotic sac or a maximum of 30 min from its rupture, Normal cardiotocogram at the time of admission and recruitment.

Exclusion criteria:

History of any incisions on the uterus, Abnormal pelvic dimensions, Abnormal bleeding, Any abnormalities in the genital soft or bone tissue, History of infertility and use of any assisted reproductive techniques in the present pregnancy, Any genital tract infection interfering with vaginal delivery (including genital herpes, fever with unknown cause, ...), Maternal medical illness (diabetes, high blood pressure, heart diseases, epilepsy, ...), Abnormal volume of amniotic fluid, Sustained asynclitisme or persistant posterior position, Severe fetal scalp edema or molding, Estimated fetal weight of more than 4000 g Known severe fetal anomalies interfering with vaginal delivery (hydrocephalus, polycystic kidney and any large abdominal mass) diagnosed, Fetal intrauterine growth restriction (IUGR), Maternal speech, hearing and visual problems.

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **351**

Randomization (investigator's opinion)

Randomized

Randomization description

A stratified (based on the two study sites) block randomization with random block sizes of 3, 6, 9 and allocation ratio of 1:1:1 will be used to assign participants into the three groups; group 1: amniotomy with early oxytocin infusion, group 2: amniotomy with delayed oxytocin infusion, and group 3: hospital routine intervention. The sequence will be generated using a computerized program (Randomizer). To conceal the sequence, consecutively numbered opaque sealed envelopes will be used. The sequence generation and preparation of the envelopes will be done by a person not involved in participant recruitment or data collection.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

At the two intervention groups, amniotomy will be done for those with intact amniotic sac. A 500 ml ringer serum will then be administered for all of the participants with a controlled infusion pump. In the group with early oxytocin infusion, 5 IU of oxytocin, and in the group with delayed oxytocin infusion, 1 ml of distilled water will be added to the solution. The infusion will be started with 3 drops/min. Then, 3 drops will be added every 20 min until reaching number of uterine contractions to 3/10 min or reaching number of the droplets to 30/min. The investigators and participants will not be aware of the type of intervention (early or delayed) within the first 3 h. In cases with occurrence of any tachycystol or abnormal cardiotocogram, the serum will immediately be replaced with a plain serum ringer. After the 3 h, the serum will be discontinued in the both early and delayed groups and a re-examination will be done by the investigator. In absence of childbirth or inadequate uterine contractions after the 3 h, 5 IU of oxytocin in 500 ml ringer serum be infused for the delayed group, in the same way mentioned for the early infusion group. The third (control) group will receive routine intervention of the hospital.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

No. 2 Central Building, Tabriz University of Medical

Sciences, Golgasht Ave., Tabriz, Iran

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Approval date
2018-10-22, 1397/07/30

Ethics committee reference number
IR.TBZMED.REC.1397.624

Health conditions studied

1

Description of health condition studied
Prolonged labor in nulliparous women

ICD-10 code
063.0

ICD-10 code description
Prolonged first stage of labour

Primary outcomes

1

Description
The interval between intervention initiation and vaginal delivery

Timepoint
After delivery

Method of measurement
Timer

2

Description
Score of maternal satisfaction with process of labor and birth

Timepoint
12-24 h after childbirth

Method of measurement
MacKey childbirth satisfaction rating scale

Secondary outcomes

1

Description
Mode of delivery

Timepoint
After delivery

Method of measurement
Using Medical record

2

Description
Uterine hyperstimulation

Timepoint
At intervals of one hour since the intervention initiation

Method of measurement
Palpation of uterine contractions for 10 min

3

Description
Maternal fever

Timepoint
Within 6 hours after delivery

Method of measurement
Thermometer (sublingual)

4

Description
Use of analgesic drugs in the first stage of labor

Timepoint
During intervention

Method of measurement
Observation and record

5

Description
Manual removal of placenta

Timepoint
After vaginal childbirth

Method of measurement
Observation

6

Description
Hemoglobin and hematocrit

Timepoint
At baseline and 12 hours after delivery

Method of measurement
Laboratory test

7

Description
Volume of postpartum hemorrhage

Timepoint
12 hours after delivery

Method of measurement
Using the Stafford formula

8

Description
Duration of the first stage of labor (from 4 to 10 cm cervical dilatation)

Timepoint
After completion of cervical dilatation

Method of measurement
Timer

9

Description
Duration of the second stage of labor (from completing cervical dilatation to fetal expulsion)

Timepoint

After fetal expulsion

Method of measurement

Timer

10

Description

Duration of the third stage of labor (from delivery of the baby until complete expulsion of the placenta)

Timepoint

After complete expulsion of the placenta

Method of measurement

Timer

11

Description

Abnormal cardiotocogram (late deceleration, variable deceleration)

Timepoint

During the intervention

Method of measurement

Cardiotocography audit sheet

12

Description

Admission in neonatal intensive care unit

Timepoint

At hospital discharge of the baby

Method of measurement

Hospital record

13

Description

Neonate Apgar score less than 7

Timepoint

5 minutes after birth

Method of measurement

Clinical examination

Intervention groups

1

Description

Intervention group 1 (early oxytocin infusion): If the amniotic sac is intact, amniotomy will be done with an amniotic hook by the investigator. Soon after, 5 IU of oxytocin in 500 ml ringer's solution will be administered by a controlled infusion pump. The infusion will be started with 3 drops/min. Then 3 drops will be added every 20 min until the number of contractions reaches 3/10 min or the number of droplets reaches 30/min.

Category

Treatment - Drugs

2

Description

Intervention group 2 (delayed oxytocin infusion): If the amniotic sac is intact, amniotomy will be done with an amniotic hook by the investigator. Soon after, a 500 ml plain ringer serum will be administered by a controlled infusion pump. The infusion will be started with 3 drops/min. Then, 3 drops will be added every 20 min. After 3 h, in absence of childbirth or inadequate uterine contractions, 5 IU of oxytocin in 500 ml ringer's solution will be infused with 3 drops/min. Then, 3 drops will be added every 20 min until the number of contractions reaches 3/10 min or the number of droplets reaches 30/min.

Category

Treatment - Drugs

3

Description

Control group: This group will receive routine intervention of the hospital that includes: amniotomy, oxytocin infusion, both, or expected management.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Medical Research & Training Hospital

Full name of responsible person

Jila Nahaee

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Web page address

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

Jila Nahaee

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Tabriz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Jila Nahaee

Position
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Latest degree
Master

Other areas of specialty/work
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All deidentified IPD can be shared.
When the data will become available and for how long
Starting soon after publication of the study results.
To whom data/document is available
Data will be available for researchers working in academic institutions, as well as to chief editor and reviewers of the submitted manuscript.
Under which criteria data/document could be used
The data will be available to researchers upon request and submission of the proposal to perform meta-analysis using IPD. Also, in exceptional cases, data will be made available to chief-editor of the journals for checking.
From where data/document is obtainable
Refer to the email addresses (jnahaee@yahoo.com, alizades@tbzmed.ac.ir).
What processes are involved for a request to access data/document
The requests should be sent by email and data will be available within two week.
Comments