

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The comparison of low dose with high dose of oxytocin in prevention of postpartum hemorrhage

Protocol summary

Study aim

Determining the effect of low oxytocin dose compared to high oxytocin dose in preventing postpartum hemorrhage

Design

Clinical trial without control group, three-way blind, randomized, phase 1 on 60 patients.

Settings and conduct

The first group will receive an oxytocin dose of 10 units per 500 cc of Ringer serum and the second group will receive 60 units of oxytocin per 500 cc of Ringer serum. We chose 10 units A dose for the intervention group and 60 units B for the intervention group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: primiparous; age 18-45 years old; gestational age 37-41 weeks; singleton pregnancy; cephalic. Exclusion criteria: history of medical and obstetric diseases; fetal malformations; fetal weight estimate over 4000 g; diagnosis of chorioamnionitis; placental abruption. Exclusion criteria during the study: first and second stage of long labor; cesarean section; labor dystocia; shoulder dystocia; prenatal bleeding; instrumental labor.

Intervention groups

The first group will receive an oxytocin dose of 10 units per 500 cc of Ringer serum and the second group will receive 60 units of oxytocin per 500 cc of Ringer serum. We chose 10 units A dose for the intervention group and 60 units B for the intervention group.

Main outcome variables

postpartum hemorrhage collected in drape sheet 2 hours after delivery; admission hematocrit and hemoglobin; hematocrit and hemoglobin 2 hours after delivery

General information

Reason for update

Acronym

OXT

IRCT registration information

IRCT registration number: **IRCT20220122053780N1**

Registration date: **2022-01-29, 1400/11/09**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-29, 1400/11/09**

Update count: **0**

Registration date

2022-01-29, 1400/11/09

Registrant information

Name

Maryam Zamani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 154 6300

Email address

zanim1@nums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-25, 1400/10/04

Expected recruitment end date

2022-05-25, 1401/03/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of low dose with high dose of oxytocin in prevention of postpartum hemorrhage

Public title

The comparison of low dose with high dose of oxytocin in prevention of postpartum hemorrhage

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Primiparous Age 18-45 years old Gestational age 37-41 weeks Singleton pregnancy Cephalic presentation

Exclusion criteria:

History of medical and obstetric diseases Fetal malformations Fetal weight estimate over 4000 g Diagnosis of cryoamniosis Placental abruption First and second stage of long labor Cesarean section Labor dystocia Shoulder dystocia Prenatal bleeding Instrumental labor

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **30**

All pregnant mothers admitted to Hakim Neishabour Hospital for normal delivery

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked Randomization with Randomly Selected Block Sizes will be used for random allocation. Through random 4, 8 and 12 blocks, each participant will be placed in one of the intervention groups. The allocation sequence will be generated using the website

<https://www.sealedenvelope.com/simple-randomiser/v1/lists> and with the help of the methodology consultant.

Since all participants are registered in a hospital (center), white envelopes will be used to hide the sequence. In this way, each sequence will be placed in a white envelope and the envelopes will be placed next to each other and the envelopes will be numbered. An envelope will be opened for each person in the order of their entry into the study and will be assigned to the groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

To blind the study (three-blind); The researcher, outcome evaluator (assistant researcher), participant and statistical analyst will not know the dose of oxytocin in serums.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Neyshabur University of Medical Sciences

Street address

Farhangian Ave., Neyshabur city

City

Neyshaur

Province

Razavi Khorasan

Postal code

93186-14139

Approval date

2021-12-25, 1400/10/04

Ethics committee reference number

IR.NUMS.REC.1400.036

Health conditions studied

1

Description of health condition studied

Postpartum hemorrhage

ICD-10 code

O72

ICD-10 code description

Postpartum hemorrhage

Primary outcomes

1

Description

Postpartum hemorrhage amount

Timepoint

Immediately after delivery and each quarter to 2 hours after delivery

Method of measurement

Using measured Drape sheets for blood collection (disposable, funnelled, plastic collector bag) and reporting to cc

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receiving 10 unit Oxytocin in 500 cc

Ringer serum
Category
Prevention

2

Description

Intervention group: Receiving 60 unit Oxytocin in 500 cc
Ringer serum

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hakim Hospital

Full name of responsible person

Maryam Zamani

Street address

Farhangian Ave., Neyshabur

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Email

zanim1@nums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Neyshabour University of Medical Sciences

Full name of responsible person

Dr. Ali Akbar Mohammadi

Street address

Farhangian Ave., Neyshabur

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Phone

+98 51 4330 6219

Email

researchnums1@gmail.com

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Neyshabour 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

Neyshabour University of Medical Sciences

Full name of responsible person

Maryam Zamani

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

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Medical Sciences Campus, Moqavmat Boulevard,
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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentifiable individuals.

When the data will become available and for how long

Start from 2021

To whom data/document is available

There is no restriction.

Under which criteria data/document could be used

There is no restriction.

From where data/document is obtainable

Maryam Zamani Zanim1@nums.ac.ir
00989151546300

What processes are involved for a request to access data/document

One week

Comments