Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The analgesic effects of Oxytocin in women undergoing cesarean section under spinal anesthesia

Protocol summary

Study aim
Evaluation of the effect of oxytocin on postoperative pain in patients undergoing cesarean section anesthesia

Design
patients divided into two groups A and B. (30 people in each group). 1.To control bleeding after placental abruption in group A, oxytocin 20 units in normal saline is injected at a rate of 10 cc per minute. If the patient needs uterotonic drug, 0.2 mg metrogen or 400 sublingual misoprostol is used. Group A will not receive oxytocin in prescription sera. 2. To control bleeding after placental abruption in group B, oxytocin is injected 20 units in normal saline at a rate of 10 cc per minute. If the patient needs, uterotonic contraceptive drug (0.2 mg of metrogen or misoprostol 400 sublingually) is given. Group B 10 units of normal saline will be added to the prescribed serums every 8 hours immediately after the operation. A total of 30 units in 24 hours).

Settings and conduct
Patients referred to Kosar Hospital in Qazvin for cesarean section are studied, then patients are divided into two groups A and B based on a table of computer random numbers (30 people in each group). This study will be performed in a double-blind manner.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients referred to Kosar Hospital in Qazvin for cesarean section/ Exclusion Criteria: History of chronic pain and analgesic use, bleeding or coagulation disorder, peptic ulcer, renal or hepatic insufficiency and asthma, uterine atony, twins, placenta previa, Placental abruption, accreta placenta

Intervention groups
In the intervention group, immediately after cesarean section, 10 units of oxytocin will be added to the prescribed serums every 8 hours per liter of normal saline (30 units in 24 hours).

Main outcome variables
Pain relief

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190905044705N1**
Registration date: **2021-12-23, 1400/10/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-23, 1400/10/02**
Update count: **0**

Registration date
2021-12-23, 1400/10/02

Registrant information
Name
Mohammadmahdi Mir Nasseri
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
2021-12-06, 1400/09/15

Expected recruitment end date
2022-03-01, 1400/12/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The analgesic effects of Oxytocin in women undergoing cesarean section under spinal anesthesia

Public title
The analgesic effects of Oxytocin
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
All patients referred for cesarean section Lack of exclusion criteria
Exclusion criteria:
History of chronic pain and analgesic use, bleeding or coagulation disorder, peptic ulcer, renal or hepatic insufficiency and asthma, uterine atony, twins, placenta previa, Placental abruption, accreta placenta
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly divided into two groups by using simple random allocation method (Random number table). Numbers extracted from tables that are odd are assigned to intervention group 1 and even numbers are assigned to control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants and outcome assessors and analysts are unaware of the study groups
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences
Street address
Qazvin University of Medical Sciences, Shahid Bahonar Boulevard, Qazvin
City
Qazvin
Province
Qazvin
Postal code
15315-34199
Approval date
2021-02-21, 1399/12/03
Ethics committee reference number
IR.QUMS.REC.1399.496

Health conditions studied

1

Description of health condition studied
Cesarean
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain after cesarean section
Timepoint
Up to 24 hours after delivery
Method of measurement
Verbal Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients referred for cesarean section. For spinal anesthesia of 0.5% bupivacaine hydrochloride (4 ml / 20 mg ampoule - Mylan made in France by Haupt Pharma Livron SAS) in the amount of 2.5 cc in the midline of the spine between 2 and 3 Or 4 and 5 lumbar vertebrae of needle number 25 will be used in a sitting position. In group B, to control bleeding after placental abruption, oxytocin is injected 20 units in normal saline at a rate of 10 cc per minute. In group B, immediately after surgery, 10 units of normal saline will be added to the prescribed serums every 8 hours (30 units in 24 hours)
Category
Treatment - Drugs

2

Description
Control group: Patients referred for cesarean section. For spinal anesthesia of 0.5% bupivacaine hydrochloride (4

ml / 20 mg ampoule - Mylan made in France by Haupt Pharma Livron SAS) in the amount of 2.5 cc in the midline of the spine between 2 and 3 Or 4 and 5 lumbar vertebrae of needle number 25 will be used in a sitting position. In group A, to control bleeding after placental abruption, oxytocin (one milliliter ampoule / 10 units - manufactured by Caspian Tamin Pharmaceutical Company) is injected 20 units in normal saline at a rate of 10 cc per minute. This group does not receive oxytocin for 24 hours after delivery.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Kosar Hospital, Qazvin

Full name of responsible person
Mohammadmahdi Mirnasseri

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Taleghani Street, next to the electricity office

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Seyd Mahdi Mirhashemi

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Shavid Beheshti Boulevard is a Sub-district of Maudat

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
معاونت تحقیقات و فناوری

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
Qazvin University of Medical Sciences

Full name of responsible person
Mohammad Mahdi Mir Nasseri

Position
Assistant of Anesthesiology

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Anestesiologist

Latest degree

Specialist

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Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The project partners have not been consulted yet

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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