

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 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 metrogren 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 metrogren 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

Country

Iran (Islamic Republic of)

Phone

+98 21 4432 1888

Email address

mirnasseri@gmail.com

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

Street address

Taleghani Street, next to the electricity office

City

Qazvin

Province

Qazvin

Postal code

34156 13176

Phone

+98 28 3323 6374

Fax

+98 28 3323 6374

Email

mirnasseri@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Seyd Mahdi Mirhashemi

Street address

Shavid Beheshti Boulevard is a Sub-district of Maudat

City

Qazvin

Province

Qazvin

Postal code

34156 13176

Phone

+98 28 3336 8124

Fax

+98 28 3335 0056

Email

research.dpt@qums.ac.ir

Web page address

<https://vcr.qums.ac.ir/fa-IR/vcr.qums.ac/9284/page/%>

D9%85%D8%B9%D8%B1%D9%81%DB%8C-
%D9%85%D8%B9%D8%A7%D9%88%D9%86%D8%A
A

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 Nasserri

Position

Assistant of Anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

No 37, First Deadlock, Seventh St., Kargar-e-Shomali Ave, Tehran, Iran.

City

Tehran

Province

Qazvin

Postal code

1439667661

Phone

44321888

Fax

+98 21 8801 2089

Email

mirnasseri@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Mohammadmahdi Mir Nasserri

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

No 37, First Deadlock, Seventh St., Kargar-e-Shomali Ave,

City

Tehran

Province

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Postal code

1439667661

Phone

+98 21 4432 1888

Fax

+98 21 8801 2089

Email

mirnasseri@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mohammadmahdi Mir Nasseri

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

No 37, First Deadlock, Seventh St., Kargar-e-Shomali Ave,

City

Tehran

Province

Tehran

Postal code

1439667661

Phone

+98 21 4432 1888

Fax

+98 21 8801 2089

Email

mirnasseri@gmail.com

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