Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The effect of rectal oxytocin suppositories compared to routine methods in reducing pain and bleeding after elective cesarean section - a randomized clinical trial

Protocol summary

Study aim
The effect of rectal oxytocin suppositories compared to routine methods in reducing pain and bleeding after elective cesarean section.

Design
In this randomized clinical trial study, pregnant women are completely randomly divided into two intervention groups of 26 people: oxytocin rectal suppository and placebo: placebo rectal suppository.

Settings and conduct
Term pregnant women candidates for elective cesarean section for the second time, referred to Kamali Hospital with the conditions for entering the study, will be randomly assigned to one of the intervention/placebo groups in two groups of 26.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Pregnant women candidates for elective cesarean surgery for the second time; 37 weeks of pregnancy and singletons; Insensitivity to oxytocin. Exclusion criteria: Hemodynamic changes during surgery; Nausea and vomiting; Respiratory arrest; Arrhythmia; Severe bleeding; The need for additional days of oxytocin or the need for other drugs such as metrogen and misopropylol; Chills and severe pain after surgery.

Intervention groups
Intervention group: In recovery, 10 units of intravenous oxytocin (per liter of serum) are injected and then rectal oxytocin suppositories are given. Suppositories contain 10 effective units of oxytocin. Placebo group: In recovery, 10 units of intravenous oxytocin (per liter of serum) are injected and then placebo rectal suppositories are given. Placebo suppositories are completely similar to medicinal suppositories in terms of shape, size and color, and in terms of composition, they contain paraffin.

Main outcome variables
Pain; Bleeding

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221011056143N1**
Registration date: **2022-10-16, 1401/07/24**
Registration timing: **prospective**

Last update: **2022-10-16, 1401/07/24**
Update count: **0**

Registration date
2022-10-16, 1401/07/24

Registrant information

Name
Mehdi Zakikhani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 26 3428 7383

Email address
mehdizakikhani۹۵@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-31, 1401/08/09

Expected recruitment end date
2023-02-17, 1401/11/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of rectal oxytocin suppositories compared to routine methods in reducing pain and bleeding after elective cesarean section - a randomized clinical trial

Public title
The effect of rectal oxytocin suppositories compared to routine methods in reducing pain and bleeding after elective cesarean section

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women candidates for elective cesarean surgery for the second time Age 20 to 40 years Full-term women (37 full weeks of pregnancy and singletons) who undergo active cesarean section for non-emergency reasons. A.S.A Class II Not suffering from underlying diseases such as diabetes, high blood pressure, preeclampsia, eclampsia or a history of taking certain drugs. Not suffering from hypothyroidism Insensitivity to oxytocin Absence of fetal anomalies No history of headache and migraine No history of taking psychotropic drugs No alcohol or drug addiction Complete mastery of official language conversation and the ability to read and write in Persian No meningitis at the time of study Not suffering from psychiatric diseases

Exclusion criteria:
Severe drop in blood pressure during cesarean section Any arrhythmia, whether tachyarrhythmia or bradyrhythmia Heavy bleeding during cesarean section Any disruption in the delivery process that prolongs the surgical process or repeats the caesarean section, including rupture of the bladder or bowels during surgery. Hemodynamic changes during surgery, nausea and vomiting, respiratory arrest, arrhythmia and severe bleeding The occurrence of shivering and severe pain in patients after surgery The need for extra days of oxytocin or the need for other drugs such as metrogen and misopropylol

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be done as a block randomization method. So, initially, in the Excel software, there are 6 blocks of 4 as (AA, BB), (BB, AA), (AB, BA), (BA, AB). (AB, AB), (BA, BA) are prepared and then these blocks will be arranged from one to six. A is the confirmation of the treatment or intervention group and B is the confirmation of the placebo group. Then one of these blocks will be randomly selected and based on the sequence of letters A and B in the selected block, the eligible people will be assigned to the treatment or placebo groups. The random process of selecting blocks and assigning people to the intervention and placebo groups will continue until the desired sample size is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
For the study subjects, before the random assignment, it is explained how the work process is and they may receive one of the two treatments randomly, and the drug used for the subjects is not known in advance, the form of the intervention drug and placebo and also, the frequency and times of administration of these two will be similar, so that it is not possible for the patient to distinguish them from each other, so the patient will not know which group she is in.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Alborz University of Medical Sciences

Street address
Second floor, Deputy of Research and Technology, Saffarian Alley, 45 meters from Golshahr, Karaj.

City
Karaj

Province
Alborz

Postal code
3149779453

Approval date
2022-05-20, 1401/02/30

Ethics committee reference number
IR.ABZUMS.REC.1401.176

Health conditions studied

1

Description of health condition studied
Pain and bleeding after Cesaean Section

ICD-10 code
O75.4

ICD-10 code description

Other complications of obstetric surgery and procedures

Primary outcomes

1

Description
Pain
Timepoint
0.5, 1, 1.5, 3.5, 6 hours after surgery
Method of measurement
Visual analog scale questionnaire

2

Description
Bleeding
Timepoint
Within 24 hours after delivery
Method of measurement
Counting gasses and blood-soaked sheets to estimate the amount of bleeding

Secondary outcomes

1

Description
Headache
Timepoint
12, 24, 48 and 72 hours after surgery
Method of measurement
visual analog scale questionnaire

2

Description
Shivering
Timepoint
20, 35, 50, 65, 80 and 95 minutes after surgery
Method of measurement
Crossley and Mahajan scale

Intervention groups

1

Description
Intervention group: In recovery, 10 units of intravenous oxytocin (per liter of serum) are injected and then rectal oxytocin suppositories are given. Suppositories contain 10 effective units of oxytocin.
Category
Prevention

2

Description
Control group: In recovery, 10 units of intravenous oxytocin (per liter of serum) are injected and then placebo rectal suppositories are given. Placebo suppositories are completely similar to medicinal suppositories in terms of shape, size and color, and in terms of composition, they contain paraffin.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Kamali Hospital
Full name of responsible person
Banafsheh Mashak MD
Street address
Shahada Square, Qazvin St.
City
Karaj
Province
Alborz
Postal code
3134877179
Phone
+98 26 3222 2021
Email
mashakbanafsheh@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Hatam Godini P.H.D
Street address
Saffarian alley, 45 meters from Golshahr, Karaj
City
Karaj
Province
Alborz
Postal code
3198764653
Phone
+98 26 3464 3705
Email
h.godini@abzums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Karaj 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
Karaj University of Medical Sciences

Full name of responsible person
Mehdi Zakikhani MD

Position
Anesthesiology resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Kamali Medical Education Center, Kamali Street, Shahada Square, Shahid Beheshti Street

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Person responsible for scientific inquiries

Contact

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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
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
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 data is potentially shareable after unidentified individuals

When the data will become available and for how long
Access period starts 6 months after the results are published.

To whom data/document is available
Research centers and faculty members

Under which criteria data/document could be used
At the request of the researcher and faculty members

From where data/document is obtainable
send email to the scientific respondent

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

Within two months from the time of requesting and sending the email, the documents will be sent to the mentioned people

Comments