Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Investigation of the effect of the intraoperative dose of intravenous dexamethasone on post-cesarean delivery analgesia in pregnant mothers referred to Kosar Educational and Medical Hospital in Qazvin 1399

Protocol summary

Study aim
The effect of intraoperative intravenous dexamethasone on post-cesarean delivery analgesia in pregnant women

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 88 patients. The method of assigning participants will be simple randomization and using the table of random numbers.

Settings and conduct
Double Blind (Patient-Resident) Qazvin Kosar Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: Gestational age>=37 weeks; Age over 18 years and no history of specific disease; Uncomplicated pregnancy; Elective C-section (breech, meconium, macrosome, repeat 2); Absence of previous laparotomy incision except C-section Exclusion criteria: contraindications to spinal anesthesia; allergy to study medications; uncontrolled hypertension; uncontrolled DM; glaucoma; IV drug abuse; chronic pain or long-term opioid use; steroid medication within the week prior to cesarean delivery; subjects with psychiatric illness that would prohibit informed consent or comprehension of the study questions; repeat 3 C-section or more than 2 laparotomies; chorioamnionitis; Intra-abdominal adhesions

Intervention groups
Dexamethasone injection to pregnant mothers; Placebo injection to pregnant mothers

Main outcome variables
Pain after cesarean section

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210110049996N1**
Registration date: **2021-03-05, 1399/12/15**
Registration timing: **prospective**

Last update: **2021-03-05, 1399/12/15**
Update count: **0**

Registration date
2021-03-05, 1399/12/15

Registrant information

Name
Seyedeh Firouzeh Aghanejad
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 28 3335 6620
Email address
f.aghanejad@qums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-06, 1399/12/16

Expected recruitment end date
2021-09-21, 1400/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation of the effect of the intraoperative dose of intravenous dexamethasone on post-cesarean delivery analgesia in pregnant mothers referred to Kosar Educational and Medical Hospital in Qazvin 1399

Public title
The effect of dexamethasone on reducing pain after cesarean section in pregnant women referred to Kosar Hospital in Qazvin 1399

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Gestational age> = 37 weeks Age over 18 years and no history of specific disease Uncomplicated pregnancy Elective cesarean section (breech, meconium, macrosome, ripit 2) Absence of previous laparotomy incision except cesarean section

Exclusion criteria:
contraindications to spinal anesthesia allergy to study medications uncontrolled hypertension uncontrolled diabetes mellitus glaucoma IV drug abuse , chronic pain or long-term opioid use steroid medication within the week prior to cesarean delivery subjects with psychiatric illness that would prohibit informed consent or comprehension of the study questions repeat 3 cesarean section or more than two laparotomies chorioamnionitis Intra-abdominal adhesions

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of allocation randomization will be Simple Randomization and using a table of random numbers. So that with equal allocation of 1: 1 ratio, they will be in one of the two groups. To select a personal sample from a table of random numbers, start surprisingly from a table point in the direction of the levels or columns. Selecting a point can be done by closing your eyes and placing your finger or the tip of a Roman pen on the table. Moving in the direction of the row or column is symbolically different. But according to the type of code (two digits) in the direction of the row or column, the same number of digits should be selected. After this, the route numbers are controlled. There will be two types of numbers, one of which is smaller than the additional number of the study population and the other is larger than the number of the population. You just have to choose the numbers. The selected number is in fact the individual code of the sample community that is selected as the sample of the selected group. This work is going on so long that the number of sample people in Group A can be 44. After completing the sample size, the experimental sample work is completed. And the selected numbers are in group B. In this way, the number of people is usually equal and randomly divided into two groups of 44 people.

Blinding (investigator's opinion)
Double blinded

Blinding description
Group assignments will be concealed in opaque sequentially-numbered envelops. After obtaining informed written consent before the operation, the anesthesiologist who will be a part of the research team will open the group assignment. The anesthetist will prescribe the drugs in the same serum as the "study drug." Researcher and patients will not be aware of the drug or placebo injection (Two groups blinded).

Placebo
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
Kowsar hospital, Kowsar Ave, Next to the Electricity Office, Taleqani Ave, Qazvin

City
Qazvin

Province
Qazvin

Postal code
3415613176

Approval date
2020-09-30, 1399/07/09

Ethics committee reference number
IR.QUMS.REC.1399.245

Health conditions studied

1

Description of health condition studied
The effect of intravenous dexamethasone injection on pain after cesarean section

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The effect of intravenous dexamethasone on pain after cesarean section

Timepoint
6,12,18,24 hour after surgery
Method of measurement
Both baseline preoperative and postoperative pain scores at rest and movement will be assessed using a numerical rating scale (NRS) (0 means “no pain” and 10 means “the worst possible pain”). Pain at rest will be assessed with the patient lying supine and pain with movement will be assessed when moving from the supine to an upright sitting position.

2

Description
Nausea
Timepoint
6,12,18,24 hour after surgery
Method of measurement
Patients will be asked to rate the severity of postoperative nausea using an 11-point numerical rating scale (NRS) from 0 to 10 (0: “no nausea” to 10: “worst nausea possible”). The number of vomiting episodes, if any during the 24-h study period, will be documented.

3

Description
Pruritus
Timepoint
6,12,18,24 hour after surgery
Method of measurement
Pruritus will be assessed using an 11-point NRS (0: “no pruritus” to 10: “worst pruritus possible”).

Secondary outcomes

1

Description
headache
Timepoint
6,12,18,24 hour after surgery
Method of measurement
Patients will be asked to rate the severity of postoperative headache using an 11-point numerical rating scale (NRS) from 0 to 10 (0: “no headache” to 10: “worst headache possible”). The number of headache episodes, if any during the 24-h study period, will be documented.

Intervention groups

1

Description
Control group: Patients in the intervention group will receive IV dexamethasone 8 mg (2 mL) after clamping the umbilical cord.
Category
Treatment - Drugs

2

Description
Control group: After clamping the umbilical cord, patients in the control group will receive IV normal saline 2 mL.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar hospital
Full name of responsible person
Seyedeh Firouzeh Aghanejad
Street address
Kowsar hospital, Kowsar Ave, Next to the Electricity Office, Taleqani Ave, Qazvin
City
Qazvin
Province
Qazvin
Postal code
3415613176
Phone
+98 28 3323 6374
Email
f.aghanejad@qums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Peyman Namdar
Street address
Kowsar Hospital, Kowsar Ave, Next to the Electricity Office, Taleqani Ave, Qazvin
City
Qazvin
Province
Qazvin
Postal code
3415613176
Phone
+98 28 3323 6374
Email
f.aghanejad@qums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Seyedeh Firouzeh Aghanejad
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Kowsar Hospital, Kowsar Ave, Next to the Electricity Office, Taleqani Ave, Qazvin
City
Qazvin
Province
Qazvin
Postal code
3415613176
Phone
+98 28 3323 6374
Email
f.aghanejad@qums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Seyedeh Firouzeh Aghanejad
Position
residency
Latest degree
Medical doctor
Other areas of specialty/work
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Province
Qazvin
Postal code
3415613176
Phone
+98 28 3323 6374
Email
f.aghanejad@qums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Seyedeh Firouzeh Aghanejad
Position
residency
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Kowsar hospital, Kowsar Ave, Next to the Electricity Office, Taleqani Ave, Qazvin
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+98 28 3323 6374
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f.aghanejad@qums.ac.ir

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
Information on pain relief, analgesia, nausea and vomiting, pruritus, headache, and infection at the incision site after dexamethasone injection is shared without specifying the patient personal information.
When the data will become available and for how long
2022 march
To whom data/document is available
It will be available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
People in the field of medicine and paramedical
From where data/document is obtainable
Dr Dadashaliha Kosar Hospital m.dadashaliha@qums.ac.ir Seyedeh Firouzeh Aghanejad

Kosar Hospital f.aghanejad@qums.ac.ir

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

If there is any request through email or hospital visiting in-person, it will be answered in 10 days.

Comments