Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

comparison of the effect of intravenous and subcutaneous Dexamethasone on prevention of pain after caesarian section

Protocol summary

Study aim
Comparison of the effect of intravenous and subcutaneous dexamethasone in the prevention of pain after cesarean section

Design
This phase 3 randomized clinical trial will be performed as a single blinded project with parallel groups on 156 pregnant women. Block randomization is done using Random allocation software.

Settings and conduct
This single-blind randomized clinical trial study with parallel groups will be performed on 156 pregnant women in Zanjan academic hospital. Patients will be randomly assigned to three groups. In this study, due to intervention during surgery, those responsible for data collection and those who evaluate the outcome and those who prepare the draft of the article will be completely unaware of the treatment protocol, because records will be completed as numbers 1, 2 or 3.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All women who are candidates for elective cesarean section and are not allergic to dexamethasone, aged between 20-45 years and no contraindications for spinal anesthesia. Exclusion criteria are prolonged cesarean section (more than 2 hours) and converting spinal anesthesia to general anesthesia for any reason.

Intervention groups
Intervention 1: Eight milligrams of intravenous dexamethasone will be given as a single dose immediately after spinal anesthesia. Intervention group 2: Eight mg subcutaneous dexamethasone will be administered to the patient as a single dose at the end of the procedure before the skin incision closure. Control group: Without dexamethasone administration

Main outcome variables
Post operative pain, Apgar of neonates

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220430054707N1**
Registration date: **2022-08-11, 1401/05/20**
Registration timing: **prospective**

Last update: **2022-08-11, 1401/05/20**
Update count: **0**

Registration date
2022-08-11, 1401/05/20

Registrant information

Name
batoul Ahmadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 24 3313 0001

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ahmadi.batoul@zums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-06, 1401/06/15

Expected recruitment end date
2022-11-24, 1401/09/03

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

comparison of the effect of intravenous and subcutaneous Dexamethasone on prevention of pain after caesarian section

Public title
comparison of the effect of intravenous and subcutaneous dexamethasone on the prevention of pain after cesarean section
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for non-emergency cesarean section Not having allergy to dexamethasone Age between20-45 Not having contraindications to spinal anesthesia
Exclusion criteria:
Prolongation of cesarean section more than 2 hours Convert spinal anesthesia to general for any reason.
Age
From **20 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **156**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization: In this study, we will use the block randomization method. The size of all blocks is equal and will be 9 (including three participants in first intervention group, three participants in second intervention group, and three participants in the control group). Random allocation software is also used to generate a random sequence of blocks.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, due to intervention during surgery, those responsible for data collection and those who evaluate the outcome and those who prepare the draft of the article will be completely unaware of the treatment protocol, because records will be completed as numbers (1, 2 or 3).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zanjan University of Medical Sciences
Street address
Zanjan University of Medical Sciences, Jomhori BLV. Azadi Squ. Zanjan
City
Zanjan
Province
Zanjan
Postal code
4513956184
Approval date
2022-05-31, 1401/03/10
Ethics committee reference number
IR.ZUMS.REC.1401.072

Health conditions studied

1

Description of health condition studied
post operative caesarian pain
ICD-10 code
O75.82
ICD-10 code description
Onset (spontaneous) of labor after 37 completed weeks of gestation but before 39 completed weeks gestation, with delivery by (planned) cesarean section

Primary outcomes

1

Description
Pain after surgery
Timepoint
During the first 24 hours after surgery, patients' pain will be assessed every 2 hours for six hours and then every six hours.
Method of measurement
The pain intensity of patients will be measured using a visual analog measurement system (VAS).

Secondary outcomes

1

Description
Apgar of neonate
Timepoint
First, Fifth and Ten minutes after birth
Method of measurement
Using the newborn Apgar scoring system

Intervention groups

1

Description
Intervention 1: Eight milligrams of intravenous dexamethasone produced by Abidi Pharmaceutical Factory will be given as a single dose immediately after spinal anesthesia.
Category
Treatment - Drugs

2

Description
Intervention group 2: Eight mg subcutaneous dexamethasone product of Abidi Pharmaceutical Factory will be administered to the patient as a single dose at the end of the procedure before the skin incision closure.
Category
Treatment - Drugs

3

Description
Control group: Without dexamethasone administration
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Mousavi Hospital in Zanjan
Full name of responsible person
Batoul Ahmadi
Street address
Ayatollah Mousavi Hospital, Gavazang Road, Zanjan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Doctor Samad Naderi
Street address
Zanjan University of Medical Sciences Campus, Dr. Yousef Sabouti Blvd., Zanjan
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Batoul Ahmadi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person
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Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Part of the data including the main and secondary outcomes can be shared.

When the data will become available and for how long
Access period starts from 2023

To whom data/document is available
Researcher in academic and scientific institutions

Under which criteria data/document could be used
Raw data is not available to individuals and upon request, the results of the requested statistical analysis will be available to individuals.

From where data/document is obtainable
Research Committee of the Vice Chancellor for Research and Technology

What processes are involved for a request to access data/document
To submit a request, it is enough to contact the responsible person of the project and send a written and signed request to her.

Comments