

# 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 Zanzan 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

##### Email address

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 between 20-45 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

##### City

Zanjan

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##### Postal code

1425678922

##### Phone

+98 24 3303 0001

##### Email

Ahamdi.batoul@zums.ac.ir

## 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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##### Phone

+98 24 3315 6141

##### Email

Nadris@zums.ac.ir

#### 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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Ayatollah Mousavi Hospital, Gavazang Blvd, Zanjan

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
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4513956184

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**Fax**  
**Email**  
Ahmadi.batoul@zums.ac.ir

## 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