

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative study of the preemptive effect of two-different doses of intravenous dexamethasone on sore throat after caesarean section under general anesthesia

#### Protocol summary

##### Study aim

Comparative determination of the preemptive effect of two-different doses of intravenous dexamethasone on sore throat after caesarean section under general anesthesia

##### Design

A randomized, double blinded, sham controlled clinical trial with 2 parallel groups design of 90 patient, enrolled between october 2023 and january 2024

##### Settings and conduct

This study will be performed on anesthesia at Beheshti Hospital of Isfahan. The patients will be divided into three groups. Except injecting dexamethasone, other conditions of anesthesia, remain consistent across all patients. Following the clamping of the umbilical cord, the first group will receive an injection of 8 mg dexamethasone, the second group will receive 4 mg dexamethasone, and the third group will receive 2 cc of normal saline. After surgery, the intensity of sore throat will be assessed. This assessment will be conducted by an individual unaware of the study details across the three groups. Both the patient and the evaluator of sore throat severity will be blinded to the type and quantity of the injected substance.

##### Participants/Inclusion and exclusion criteria

Entry requirements: 1. Pregnant women with ASA II older 18 years and with gestational age 37-42 weeks who are candidate for caesarean section under general anesthesia 2. Patient's Informed consent for participate in the research study Non-entry conditions: 1. Patients who are suffering from sore throat before anesthesia 2. Use of painkiller before surgery 3. Patients who have used corticosteroid during pregnancy 4. Patients who are allergic to the drug that is used in the research study 5. Difficult intubation

##### Intervention groups

First group will receive dexamethasone 8 mg; Second

group will receive dexamethasone 4 mg; Third group will receive normal saline

##### Main outcome variables

duration of intubation; duration of extubation; intensity of sore throat; kind of intervention

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230716058799N1**

Registration date: **2023-08-20, 1402/05/29**

Registration timing: **prospective**

Last update: **2023-08-20, 1402/05/29**

Update count: **0**

##### Registration date

2023-08-20, 1402/05/29

##### Registrant information

##### Name

Fatemeh Dadvar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3776 9484

##### Email address

f.dadvar.ir@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-22, 1402/06/31

##### Expected recruitment end date

2023-11-21, 1402/08/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparative study of the preemptive effect of two-different doses of intravenous dexamethasone on sore throat after caesarean section under general anesthesia

**Public title**

Comparative study of the preemptive effect of two-different doses of intravenous dexamethasone on sore throat after caesarean section under general anesthesia

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Pregnant women with ASA (American Society of Anesthesiologists) II older 18 years and with gestational age 37-42 weeks who are candidate for caesarean section under general anesthesia Patient's Informed consent for participate in the research study

**Exclusion criteria:**

Patients who are suffering from a cold or sore throat before anesthesia Patients with BMI more than 40 Use of painkiller and sedative drugs before surgery Patients who have used corticosteroid during pregnancy Patients who are allergic to the drug that is used in the research study Patients who have asthma or lung disease in their past medical history patients who have grade 3 or 4 in laryngoscopy grading (difficult intubation)

**Age**

From **18 years** old to **55 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description**

We will explain to the participate that she will be entered one of the three groups; but she can't understand the dose and kind of substance that is used during anesthesia. Also the person who will assessment the severity of sore throat, doesn't know the kind and dose of the substance.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences

**Street address**

Floor 4, No. 487, Saadat St., Dr hesabi St., janbazan St., Keshavarz Blvd.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174799898

**Approval date**

2023-03-30, 1402/01/10

**Ethics committee reference number**

IR.MUI.MED.REC.1402.012

**Health conditions studied****1****Description of health condition studied**

Sore throat

**ICD-10 code**

J04.2

**ICD-10 code description**

Acute laryngotracheitis

**Primary outcomes****1****Description**

Sore throat score base on VAS (Visual Analogue Scale)

**Timepoint**

The intensity of sore throat will be assessed at the first, 6th, 12th and 24th hours after tracheal tube removal

**Method of measurement**

Visual Analogue Scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: The first group will receive an injection of 8 mg dexamethasone intravenous, after

umbilical cord clamping  
**Category**  
Prevention

## 2

**Description**  
Intervention group: The second group will receive an injection of 4 mg dexamethasone intravenous, after umbilical cord clamping

**Category**  
Prevention

## 3

**Description**  
Control group: The 3rd group will receive an injection of 2cc normal saline intravenous, after umbilical cord clamping

**Category**  
Placebo

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Beheshti hospital  
**Full name of responsible person**  
Mitra jabalameli  
**Street address**  
Alzahra hospital, Soffeh Blvd  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8174675731  
**Phone**  
+98 31 3620 2020  
**Fax**  
+98 31 3668 4510  
**Email**  
Alzahra@mui.ac.ir  
**Web page address**  
<http://www.Alzahra.mui.ac.ir>

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Gholamreza Askari  
**Street address**  
Hezarjerib Avenue  
**City**  
Isfahan  
**Province**

Isfahan  
**Postal code**  
7346181746  
**Phone**  
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**Fax**  
+98 31 3668 8597  
**Email**  
vcr-office@med.mui.ac.ir  
**Web page address**  
<https://med.mui.ac.ir>  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Esfahan 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**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Mitra Jabalameli  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Alzahra hospital, Soffeh Blvd.  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
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**Phone**  
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**Email**  
jabalameli@med.mui.ac.ir  
**Web page address**  
<http://Alzahra.mui.ac.ir>

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mitra jabalameli

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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Alzahra hospital, Soffeh Blvd.

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http://Alzahra.mui.ac.ir

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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**

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**

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**

Individual participant data: All data can be shared after Unidentifiable individuals. Study protocol file can be shared after finishing the study. Statistical analysis map file can be shared after finishing the study. Informed consent form can be shared after finishing the study. Clinical study report can be shared after finishing the study.

**When the data will become available and for how long**

Start access the information 6 month after Publication of results

**To whom data/document is available**

The data is available for researchers are working in academic Institutions and also the persons are working in industry.

**Under which criteria data/document could be used**

Using the data in other researches is Allowed after mention the source.

**From where data/document is obtainable**

Dr. Mitra Jabalameli: jabalameli@med.mui.ac.ir Dr. Reyhanak Talakoub: talakoub@med.mui.ac.ir Fatemeh Dadvar: f.dadvar.ir@gmail.com

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

At the first, the applicant introduce herself/himself and mention the goal of receiving of the data by sending email. After proving the truth, the data will send for him/her.

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mitra Jabalameli

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Associate professor

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Specialist

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