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 dexamethason, 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 receve normal salin

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
Isfehan
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 3td group will receive an injection of 2cc normal salin 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

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8174675731

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Fax

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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

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Province

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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

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

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Person responsible for scientific inquiries

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Position
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Specialist
Other areas of specialty/work
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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 recieving of the data by sending email. After proving the truth, the data will send for him/her.
Comments