

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Ropivacaine combination with Dexamethasone analgesic effect and Ropivacaine combination with dexmedetomidine on pain after cesarean section by TAP Block method

Protocol summary

Study aim

Comparison of Ropivacaine combination with Dexamethasone analgesic effect and Ropivacaine combination with dexmedetomidine on pain after cesarean section by TAP Block method

Design

The study will have two 50 member groups. Random block randomization will be done by statistical software. The Phase 3 clinical trial study will be performed on 100 patients.

Settings and conduct

Study place: Delivery ward of Ayatollah Mousavi Hospital in Zanjan; Type of blinding: single-blind. How to blind: Patients will not be informed about the injected drug for bilateral block and only the researcher and the person injecting the drug are aware of this.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ASA(American Society of Anesthesiologists) grade 1 or 2; Ability to report the patient of his pain by the standard visual analog scale(VAS); Conscious satisfaction with the patient to participate in the study; Candidate for cesarean section under anesthesia with TAP(transverse abdominis plane) block. Non-inclusion criteria: history of anaphylaxis to dexmedetomidine or ropivacaine; history of substance abuse; History of coagulopathy

Intervention groups

Intervention group 1: Ropivacaine + dexmedetomidine will receive 15 cc of 2% ropivacaine with 100 micrograms of dexmedetomidine by bilateral TAP block method. Intervention group 2: Ropivacaine + dexamethasone by bilateral TAP block method will receive 15 cc of 2% ropivacaine with 2 cc of dexamethasone.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210302050553N1**

Registration date: **2021-05-14, 1400/02/24**

Registration timing: **prospective**

Last update: **2021-05-14, 1400/02/24**

Update count: **0**

Registration date

2021-05-14, 1400/02/24

Registrant information

Name

Mohammad Hadi Molseghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3313 1851

Email address

molseghi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

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

Comparison of Ropivacaine combination with Dexamethasone analgesic effect and Ropivacaine combination with dexmedetomidine on pain after cesarean section by TAP Block method

Public title

Comparison of analgesic effect of ropivacaine with dexamethasone and ropivacaine with dexmedetomidine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ASA(American Society of Anesthesiologists) grade 1 or 2
The patient's ability to report the extent of their pain by criteria VAS(visual analog scale) Conscious consent of the patient to participate in the study Candidate for cesarean section under anesthesia with TAP(transverse abdominis plane) block

Exclusion criteria:

History of anaphylaxis to dexmedetomidine or ropivacaine History of drug abuse History of coagulopathy

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization of patients will be random block. Based on the calculated sample size, the sample size in each group is 25 patients. positions are considered as 6 positions according to 2 groups: AABB, ABAB, BBAA, BABA, BAAB, ABBA. The positions are written on 6 cards and the selection of positions and their order will be randomly selected among the cards. The order of exit of the cards is written and will determine the order of recruitment of intervention groups based on it. Individuals will be assigned on a per-shift basis. An individual randomization unit will be used for the study. The information of registered persons will be anonymous and without their personal information.

Blinding (investigator's opinion)

Single blinded

Blinding description

Pregnant women participating in the study will be unaware of the type of drug used to perform the TAP block and will not be given any information about the drug used at the time of injection, and only the researcher and injector will be informed of the type of drug.

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 Science

Street address

Gavazang

City

Zanjan

Province

Zanjan

Postal code

4513956183

Approval date

2021-04-11, 1400/01/22

Ethics committee reference number

IR.ZUMS.REC.1400.022

Health conditions studied

1

Description of health condition studied

Post procedural pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

Pain of patients after cesarean section

Timepoint

24 hours after surgery

Method of measurement

By visual analog scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Bilateral block method by transverse abdominis plane, 15 cc of 2% ropivacaine, and 100

micrograms of dexmedetomidine will be injected between the transverse abdominis and rectus abdominis muscles.

Category

Treatment - Drugs

2**Description**

Intervention group: Bilateral block method by transverse abdominis plane, 15 cc of 2% ropivacaine 2% with 2 cc of dexamethasone will be injected between the transverse abdominis and rectus abdominis muscles.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ayatollah Mousavi Hospital

Full name of responsible person

Mohammad Reza Jamshidi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

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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

Mohammad Reza Jamshidi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Anesthesiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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