Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 rupivacaine with dexamethasone and rupivacaine 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

Street address
Gavazang

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4513956183

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+98 24 3313 0000

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mr.jamshidi47@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
Alireza Shoghli

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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
Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

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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