Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

The effect of dexmedetomidine infusion on the treatment of intraoperative shoulder pain in diagnostic laparoscopic gynecological procedures under spinal anesthesia

Protocol summary

Study aim

Investigating the effect of intravenous infusion of dexmedetomidine on the treatment of intraoperative shoulder pain in diagnostic laparoscopic surgeries of women with spinal anesthesia

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 70 patients. Using the online software available at www.start.vbc.ca/nrolin/statssize/bz.htmf, patients will be entered into one of two groups of 35 people.

Settings and conduct

In Tabriz alzahra hospital in 1402, the effect of dexmedetomidine injection on shoulder pain in diagnostic laparoscopic surgery will be evaluated in randomly assigned to intervention and placebo groups. Patients and data recorders will be blinded to the study

Participants/Inclusion and exclusion criteria

-Female with physical status II or ASA class I, candidate for diagnostic laparoscopic surgery for women in the age range of 18-60 years. -Patient consent to enter the study. Criteria for not entering the study: -The presence of any regional anesthesia contraindications. -Hypersensitivity to local anesthetics and dexmedetomidine. -excessive obesity. -Associated systemic diseases such as any history of cardiovascular, pulmonary, liver, kidney disease ande ... -Patient dissatisfaction.

Intervention groups

The effect of dexmedetomidine on shoulder pain in diagnostic laparoscopic surgery group intervention (n=35)and the control group (placbo)(n=35) would be compared

Main outcome variables

All study data will be collected through a questionnaire prepared for this purpose and will be analyzed using SPSS24 statistical software.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221116056524N1**
Registration date: **2023-06-24, 1402/04/03**
Registration timing: **retrospective**

Last update: **2023-06-24, 1402/04/03**
Update count: **0**

Registration date

2023-06-24, 1402/04/03

Registrant information

Name

Hossein Ebrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 939 904 3693

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of dexmedetomidine infusion on the treatment of intraoperative shoulder pain in diagnostic laparoscopic gynecological procedures under spinal anesthesia

Public title

The effect of dexmedetomidine infusion on the treatment of intraoperative shoulder pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Female with physical status ASA class I.II, candidate for diagnostic laparoscopic surgery for women in the age range of 18-60 years in Al-Zahra Hospital, Tabriz Patient consent to enter the study

Exclusion criteria:

Presence of any regional anesthesia contraindications, sensitivity to local anesthetics and dexmedetomidine excessive obesity Associated systemic diseases such as any history of cardiovascular, pulmonary, liver, kidney and etc. Patient dissatisfaction

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

This study will be a prospective and randomized double-blind clinical trial, after obtaining the approval of the ethical committee and obtaining written informed consent from the patient, a number of 70 women aged 18-60 years with physical status ASA I, II (American Society of Anesthesiologists), female that candidates for diagnostic laparoscopic surgery will be randomly divided into two groups. By using the online software available at www.start.vbc.ca/nrolin/statssize/bz.htmf, patients will be entered into one of two groups of 35 people.

Blinding (investigator's opinion)

Double blinded

Blinding description

In group A patients, before spinal anesthesia, intravenous bolus dexmedetomidine 1µg/kg was injected within ten minutes and then the infusion of dexmedetomidine 0.5 µg/kg/h was started, and in group B patients, infusion with the same volume and dose of 0.9 % sodium chloride serum was started as placebo by the anesthesiologist in charge of the procedure and will be continue until the patient is delivered to the PACU.All the operations will be performed by respected female surgeons who are at the same level of skill and experience. Vital signs of the patient including blood pressure, heart rate, SPO2, RR and ETCO2 upon entering the operating room, after dexmedetomidine bolus injection, before spinal anesthesia, after spinal anesthesia, before pneumoperitoneum, during pneumoperitoneum, after Trendelenberg positioning, then it will be recorded every 5 minutes until the end of the procedure and after emptying the intra-abdominal gas and transferring the patient to the PACU. Also, the severity of shoulder or abdominal pain, based on VAS score and degree of sedation according to Ramsay sedation score (with the aim of maintaining a score of 2-3) will be recorded every 10 minutes until the end of surgery and in the PACU.Also, other side effects (respiratory depression, difficulty breathing, nausea and vomiting, chills, itching) will also be recorded and treated. Possible complications during surgery such as hypertension ,hypotension, bradycardia is recorded in all of the patients, and Also, the severity of shoulder or abdominal pain, based on VAS score and degree of sedation according to Ramsay sedation score (with the aim of maintaining a score of 2-3) will be recorded every 10 minutes until the end of surgery and in the PACU.Also, other complications (respiratory depression, difficulty breathing, nausea and vomiting, chills, itching) will also be recorded and treated. The duration of surgery and anesthesia and the time between the delivery of the patient in the PACU and obtaining full recovery parameters and the possibility of delivery to the ward will be recorded in both groups. Also, the satisfaction of the patient and the surgeon (in the form of non-satisfaction, moderate satisfaction, complete satisfaction) will also be recorded at the end of the surgery.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Department of anesthesiology, alzahra hospital, south artesh street

City

Tabriz

Province

East Azarbaijan

Postal code

5174815811

Approval date

2022-05-11, 1401/02/21

Ethics committee reference number

IR.TBZMED.REC.1401.137

Health conditions studied

1

Description of health condition studied
The effect of dexmedetomidine infusion on the treatment of intraoperative shoulder pain
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Intraoperative shoulder pain in women's diagnostic laparoscopic surgeries
Timepoint
The severity of shoulder and abdominal pain, based on Visual Analogue Scale score and degree of sedation according to Ramsay sedation score, is recorded every 15 minutes until the patient's full recovery and delivery to the ward, and in case of Visual Analogue Scale scores higher than 3, the patient's pain will be treated with painkillers. The dosage of additional drugs will also be recorded
Method of measurement
Based on Visual Analogue Scale score and Grade Sedation with Ramsay sedation score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:In 35 women, before entering the operating room and after initial monitoring and before spinal anesthesia, intravenous bolus dexmedetomidine 1µg/kg was injected within ten minutes and then the infusion of dexmedetomidine 0.5µg/kg/h was started and its effect on pain The shoulder will be checked.
Category
Treatment - Drugs

2

Description
Control group: In 35 women, before spinal anesthesia, upon entering the operating room and after initial monitoring, one milliliter of sodium chloride 0.90% was injected intravenously as a placebo and its effect on shoulder pain will be investigated.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Reyhaneh abri
Street address
Alzahra hospital, south artesh street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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International relations office, NO 2 central building, Tabriz University of medical sciences, University street,Tabriz
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research-vice@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
TABRIZ 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
Tabriz University of Medical Sciences

Full name of responsible person
Reyhaneh abri

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for scientific inquiries

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Position
Assistant professor

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Person responsible for updating data

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Position
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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All potential data can be shared after making peoples unrecognizable.

When the data will become available and for how long
Starting 6 months after publication

To whom data/document is available
Documents will be available for people working in academic institutions and also people working in businesses

Under which criteria data/document could be used
There will be no specific limitations to the utilization of the data

From where data/document is obtainable
Dr .Reyhaneh Abri, Department of Anesthesiology, Faculty of Medicine, Golgasht Street, Tabriz East Azarbaijan Islamic Republic of Iran ,Phone+98 413 3341994, Fax+98 41 33341994 , re.abri@tbzmed.ac.ir

What processes are involved for a request to access data/document
Applicants will access the data from the present study by sending an email to the responsible author for a maximum of one week

Comments