Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Premedication with Oral Clonidine and Infusion of Dexmedetomidin on Perioperative Hemodynamic Responses and Analgesic requirements Post Gynecologic Laparoscopic Surgeries

Protocol summary

Study aim

The aim of this study is to compare the hemodynamic effects and postoperative analgesia of clonidine with dexmedtomidine premedication of gynecologic laparoscopic surgeries

Design

Sixty Patients were randomly assigned to either intervention or control group using online randomization software.

Settings and conduct

Sixty ASA classes I & II patients schedule for laparoscopic procedures in operating room of Tabriz obestetric&gynecology Alzahra hospital will be divided into two groups of 30. Group one will be received Dexmedtomidine 1 µg/kg in 20 ml normal saline over 10 minute immediately before anesthesia and group two will be received oral clonidine 0.2 mg 90 minute before anesthesia . Patients of group one will be received a tablet as placebo 90 minutes before surgery and group two will be administered 20 ml normal saline as placebo over 20 minutes before induction of anesthesia.Patients hemodynamic and postoperative pain will be checked and recorded according to visual analog scale in two groups. scores higher than 4 will be treated with 0.5-1 mg/kg intravenous meperidine. The person who will evaluate the patients(outcome assessor) , will be blinded to the administered medications.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients candidate for gynecologic surgery Exclusion criteria: patients with ASA class III or higheq

Intervention groups

Group one will be receiving 0.2 mg oral clonidine before operation. Group two will be receiving 1 µg/kg infusion of Dexmedtomidine over 10 minute immediately before operation.

Main outcome variables

Severity of pain which will evaluated by visual analogue scale for pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120907010765N14**
Registration date: **2019-03-13, 1397/12/22**
Registration timing: **retrospective**

Last update: **2019-03-13, 1397/12/22**
Update count: **0**

Registration date

2019-03-13, 1397/12/22

Registrant information

Name

Sousan Rasooli

Name of organization / entity

Alzahra hospital/Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 1553 9161

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Recruitment status

Recruitment complete

Funding source

Research Center, Tabriz University of Medical Silences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Premedication with Oral Clonidine and Infusion of Dexmedetomidin on Perioperative Hemodynamic Responses and Analgesic requirements Post Gynecologic Laparoscopic Surgeries

Public title

Perioperative Hemodynamic Responses and Analgesic requirements Post Gynecologic Laparoscopic Surgeries

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

patients will be schedule to gynecologic laparoscopy patients who accept for taking part in the study patients aged 20-40 patients with ASA class I or II

Exclusion criteria:

patients with ASA class III or higher cardiovascular disease neurological disease renal or hepatic disease diabetics addicts

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

1-2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

By Randomly Permuted Blocks method and using online randomization software, Patients were randomly assigned to one of the intervention groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding of the intervention will be applied in a double-blinding procedure, such that the patients were unaware from the administered medicine and the anesthesiologists who is responsible for the induction of anesthesia will be administered the study medications to the patients ,then the outcome assessor (the one who were blinded about the administered drugs)will be evaluate patients pain and sedation score and hemodynamic status.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Scienses,Golgasht Ave,Tabriz,Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5157611134

Approval date

2016-07-04, 1395/04/14

Ethics committee reference number

IR.TBZMED.REC.1395.414

Health conditions studied

1

Description of health condition studied

Laparoscopic surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of Postoperative Pain

Timepoint

evaluation of the severity of postoperative pain immediately after operation(approximately 1-2 hours after drug administration related to the operation time) in recovery ,then every 30 minutes until patients transfer to the ward

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

Intra and Postoperative Blood pressure

Timepoint

15 minutes after drug administration ,then every 15 minutes until patients transfer from recovery to the ward

Method of measurement

Non invasive monitoring of blood pressure with blood pressure monitor

Intervention groups

1

Description
Group one will be received infusion of 1 µg/kg Dexmedtomidine in 20 ml normal saline over 10 minute immediately before operation
Category
Treatment - Drugs

2

Description
Group two will be received an oral tablet of 0.2 mg Clonidine 90 minute before operation.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Obstetric and Gynecologic Hospital
Full name of responsible person
Farnaz Moslemi Tabrizi
Street address
Alzahra hospital,South Artesh ave,Tabriz,Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor of Tabriz University of Medical Sciences
Full name of responsible person
Dr.Ata Mahoudpour
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Vice Chancellor of Tabriz University of Medical Sciences, Golgasht Ave
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moslemifa@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor of 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
Vice Chancellor of Tabriz University of Medical Sciences
Full name of responsible person
Farnaz Moslemi Tabrizi
Position
Professor of Anesthesiology
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Position

Associated professor of Anesthesiology

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Web page address

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

Shared data/documents in this study include patients characteristics(demographic data)and those information related to the primary outcome(s). All patients private data like name.surname,file number will not be shared and completely remained closed.

When the data will become available and for how long

starting 1 year after publication.

To whom data/document is available

people working in academic institutions can be apply to receive it.

Under which criteria data/document could be used

criteria for using the information/documents including remaining them completely private and closed .They can be used only for comparison with other data and studies.

From where data/document is obtainable

the applicants can get the documents via corresponding author email address and contact with him/her.

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

After email contact with corresponding author and Set the schedule for time(at most 2 weeks)data will be sent as a computer file to the email address of the applicant(s).

Comments