

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Effect of intravenous dexmedetomidine on control of blood pressure after laparotomy surgery in hypertensive patients

Protocol summary

Study aim

The Effect of Dexmedetomidine on Hypertension in Patients with Hypertension after Laparotomy Surgery

Design

Double blind randomized clinical trial

Settings and conduct

This study was performed on 80 ASA class II-III patients aged 17-70 years who had a history of hypertension (hypertension above 150/90 mmHg) and were candidates for elective laparotomy after obtaining informed consent from the patient and the university's ethical committee. The fact that the patient can withdraw from the project at any time will be carried out at the Imam Reza Hospital in Tabriz. The patient will be given an anesthetic induction and the same anesthesia will continue. The patients (group D) 15 minutes before the end of the operation (beginning of abdominal cavity) 0.5 mic g / kg dilatated dexmedetomidine in 5 ml normal saline and in the control or control group (S) the amount of normal saline was only slow IV injections. The blood pressure is measured before and after the injection. After the extubation, the patient is transferred to the recovery with spontaneous respiration and is monitored and oxygenated with a face mask. Blood pressure and pain in the patient as well as agitation in both groups are recorded in the leaf. After confirming the recovery and emergency anesthetic expert, the patient is taken to the bracelet and again the blood pressure and agitation are first recorded every 15 minutes (up to 2 hours) and then every 2 hours.

Participants/Inclusion and exclusion criteria

Inclusion: hypertension history; laparotomy surgery history; has not addiction. No entry: patient refusal; opiate addiction.

Intervention groups

The intervention group who received Dexmedetomidine and control group who receive normal salin (placebo)

Main outcome variables

Blood pressure; pain; agitation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150217021121N3**

Registration date: **2018-09-18, 1397/06/27**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-18, 1397/06/27**

Update count: **0**

Registration date

2018-09-18, 1397/06/27

Registrant information

Name

Reza Movassaghi Gargari

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 8740

Email address

movassaghir@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-25, 1396/04/04

Expected recruitment end date

2018-04-22, 1397/02/02

Actual recruitment start date

2017-08-06, 1396/05/15

Actual recruitment end date

2018-09-22, 1397/06/31

Trial completion date

2018-12-21, 1397/09/30

Scientific title

Effect of intravenous dexmedetomidine on control of blood pressure after laparotomy surgery in hypertensive patients

Public title

Dexmedetomidine after laparotomy surgery

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

History of hypertension Candidate for elective laparotomy

Exclusion criteria:

Age under 18 and over 70 years old Addiction Severe systemic disabling Mental illness and chronic pain disorders Patients with ASA class III and more and patient refusal

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **76**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomly divide the patients into two groups, Random Allocation Software was used. And the patients were divided into two groups of control and medication

Blinding (investigator's opinion)

Double blinded

Blinding description

The surgeon and the patient do not know the type of group in this study, but the anesthetist knows about this study and the drugs and after examining the case number and the patient's name and medications will checked

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

Imam Reza Hospital Golghasht Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5165739431

Approval date

2018-07-23, 1397/05/01

Ethics committee reference number

ir.tbzmed.rec.1397.343

Health conditions studied**1****Description of health condition studied**

Blood pressure after laparotomy surgery in hypertensive patients

ICD-10 code

I10

ICD-10 code description

Hypertension

Primary outcomes**1****Description**

Controlling of blood pressure after laparotomy surgery in hypertensive patients

Timepoint

It is first recorded every 15 minutes (up to 2 hours) and then every 2 hours after the operation

Method of measurement

Mercury pressure gauge device

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In the patients studied group ,15 minutes before the end of surgery (starting to close the abdomen) 0.5 mic g / kg dexmedetomidine diluted in 5 ml of normal saline , slowly IV injected .

Category

Prevention

2**Description**

Control group: In the control group ,15 minutes before the end of surgery (starting to close the abdomen) only 5

ml of normal saline , slowly IV , injected.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Reza Movassaghi Gargari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Ata Mahmoudpor (Deputy of research and technology)

Street address

Tabriz University of Medical sciences,Medicine Faculty,Department of Anesthesiology

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rz_movassaghi@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

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

Dr Reza Movassaghi

Position

Associate professor of Department of Anesthesiology

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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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

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

Yes - There is a plan to make this available

Title and more details about the data/document

dexmedetomidine study data

When the data will become available and for how long

Data will be inaccessible to the public

To whom data/document is available

Those who request access to data

Under which criteria data/document could be used

Data will be available for use in meta-analysis

From where data/document is obtainable

first author

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

Requests must be sent to the first author

Comments