

# 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

**Street address**

Imam Reza Hospital Golghasht Avn

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5165739431

**Phone**

+98 41 3336 8740

**Email**

movassaghir@tbzmed.ac.ir

**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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5165665931

**Phone**

+98 41 3336 8740

**Email**

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

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Reza Movassaghi Gargari

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**Other areas of specialty/work**

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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**