

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Effect of Intravenous Dexmedetomidine on Post-Operative Pain in Patients undergoing Total Abdominal Hysterectomy

Protocol summary

Study aim

To investigate the effects of Dexmedetomidine on post-operative pain in patients undergoing Total Abdominal Hysterectomy (TAH).

Design

Randomised, controlled, parallel group trial with blinded outcome assessment. Randomisation will be done with simple randomization with random number tables

Settings and conduct

Seventy patients in age group 35 to 65 years are randomly divided using random digits table into control and intervention groups (n=35 cases). Researchers responsible for data collection and analyses are blind to the groups allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria are female patients (range age 35-65 years) candidate of Total Abdominal Hysterectomy (TAH), Body mass index (BMI): 18 to 40 kg/m², and the ASA class I, II; The exclusion criteria are allergic reaction to Dexmedetomidine, history of Dexmedetomidine administration over the past week, history of heart, lung, liver, and kidney diseases, patients with neurological or neuromuscular disorders, patients with anemia or bleeding disorders, consumption of Alcohol, narcotic and Antipsychotic medications, and patients with diabetes.

Intervention groups

Anesthesia is performed in all patients with the same drugs, including Midazolam (0.3 mg/kg), Fentanyl (3 mg/kg), Thiopental (5 mg/kg), Atracurium (0.5 mg/kg). In the Intervention group, immediately after the induction, Dexmedetomidine with a bolus dose of (1 µg/kg) is injected for 15 minutes and then infusion is done with a dose of (0.5 µg/kg) until the end of surgery. In the control group, immediately after the induction, normal saline with a dose of (1 µg/kg) is injected for 15 minutes and then infusion is done with a dose of (0.5 µg/kg) until the end of surgery.

Main outcome variables

The postoperative pain, mean arterial pressure and heart

rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190222042805N1**

Registration date: **2019-06-27, 1398/04/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-27, 1398/04/06**

Update count: **0**

Registration date

2019-06-27, 1398/04/06

Registrant information

Name

Negin Babadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Effect of Intravenous Dexmedetomidine on Post-Operative Pain in Patients undergoing Total Abdominal Hysterectomy
Public title	Intravenous Dexmedetomidine on Post-Operative Pain in Patients Candidate of Surgery
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Female candidate of Total Abdominal Hysterectomy (TAH) Age range 35-65 years Body mass index (BMI): 18 to 40 kg/m2 American Society of Anesthesiologists (ASA) classification I , II Exclusion criteria: Allergic reaction to Dexmedetomidine History of Dexmedetomidine administration over the past week History of heart, lung, liver, and kidney diseases Patients with neurological or neuromuscular disorders Patients with anemia or bleeding disorders Patients with anemia or bleeding disorders Consumption of Alcohol, narcotic and Antipsychotic medications Patients with diabetes
Age	From 35 years old to 65 years old
Gender	Female
Phase	3
Groups that have been masked	Data analyser
Sample size	Target sample size: 70
Randomization (investigator's opinion)	Randomized
Randomization description	Individuals are randomly divided into two groups based on simple randomization method using random digits table. In this method, a collection of non-template numbers is randomly generated and arranged as a table. Even numbers for the intervention group and the odd numbers for the control group are considered. According to the number of patients, they are randomly assigned to one of the treatment or intervention groups.
Blinding (investigator's opinion)	Single blinded
Blinding description	Responsible for collecting data, data analyzer
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Research deputy, Ahvaz Jundishapur University Of Medical Sciences, Golestan Blvd.

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Approval date

2018-03-17, 1396/12/26

Ethics committee reference number

IR.AJUMS.REC.1397.454

Health conditions studied

1

Description of health condition studied

Abdominal Hysterectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Post-operative pain

Timepoint

1, 2, 4, 8, 16 and 24 hours after the completion of the surgical operation

Method of measurement

The Visual Analog Scale (VAS)

2

Description

Mean Arterial Pressure (MAP)

Timepoint

Before anesthesia induction (pre-intervention), after intubation, every 15 minutes until the end of the recovery period

Method of measurement

Gauge pressure

3

Description

Heart rate

Timepoint

Before anesthesia induction (pre-intervention), after intubation, every 15 minutes until the end of the recovery period

Method of measurement

Electrocardiograph signal

Secondary outcomes

empty

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

Intervention group: Immediately after the induction, Dexmedetomidine with a bolus dose of (1 µg/kg) is injected for 15 minutes and then infusion is done with a dose of (0.5 µg/kg) until the end of surgery

Category

Treatment - Drugs

2**Description**

Control group: Immediately after the induction, normal saline with a dose of (1 µg/kg) is injected for 15 minutes and then infusion is injected with a dose of (0.5 µg/kg) until the end of surgery

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Grant name**Grant code / Reference number**

PAIN-9707

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

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Negin Babadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Person responsible for updating data**Contact****Name of organization / entity**

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