

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effect of Intravenous Dexmedetomidine on Inflammatory factors in Patients undergoing Total Abdominal Hysterectomy

Protocol summary

Study aim

To investigate the effects of Dexmedetomidine on the inflammatory factors in patients undergoing Total Abdominal Hysterectomy (TAH).

Design

Randomised, controlled, parallel group trial with blinded outcome assessment. Randomisation was centralised with simple randomization with random number tables.

Settings and conduct

Forty patients undergoing Total Abdominal Hysterectomy are randomly divided into control and intervention groups in Ahvaz Imam Khomeini hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria are females candidate of Total Abdominal Hysterectomy, Age < 65, Body mass index: 18 to 40 kg/m², and the ASA grade 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 neuromuscular disorders, patients with anemia or bleeding disorders, consumption of Alcohol, narcotic and Antipsychotic medications, and patients with diabetes.

Intervention groups

Forty patients are randomly divided into control and intervention groups (n=20 cases). In the Intervention group, immediately after the induction, Dexmedetomidine with a bolus dose of (1 µg/kg) is injected for 15 mins 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

ESR, C- Reactive Protein, Leukocytosis and Blood Glucose is measured by blood test at 30 mins before anesthesia induction (pre-intervention), 1 hour after the start of surgery, immediately, 6 and 24 hours after the completion of the surgical operation. MAP and HR are

recorded before intervention, after intubation, every 15 minutes until the end of the recovery period.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180506039558N1**

Registration date: **2018-07-28, 1397/05/06**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-28, 1397/05/06**

Update count: **0**

Registration date

2018-07-28, 1397/05/06

Registrant information

Name

Maryam Derakhshani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 2818

Email address

derakhshani.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Intravenous Dexmedetomidine on Inflammatory factors in Patients undergoing Total Abdominal Hysterectomy

Public title

Intravenous Dexmedetomidine on Inflammatory Mediators in Patients candidate of Surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Female candidate of Total Abdominal Hysterectomy (TAH) 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 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

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with random number tables

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

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

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2018-04-21, 1397/02/01

Ethics committee reference number

IR.AJUMS.REC.1394.718

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

Abdominal Hysterectomy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Quantitative evaluation of C- Reactive Protein

Timepoint

30 minutes before anesthesia induction (Before intervention), 1 hour after the start of operation, Immediately, 6 and 24 hours after the completion of the operation

Method of measurement

Blood test

2**Description**

Quantitative evaluation of ESR

Timepoint

30 minutes before anesthesia induction (Before intervention), 1 hour after the start of operation, Immediately, 6 and 24 hours after the completion of the operation

Method of measurement

Blood test

3**Description**

Quantitative evaluation of Leukocytosis

Timepoint

30 minutes before anesthesia induction (Before intervention), 1 hour after the start of operation, Immediately, 6 and 24 hours after the completion of the operation

Method of measurement

Blood test

4

Description

Quantitative evaluation of Blood Glucose

Timepoint

30 minutes before anesthesia induction (Before intervention), 1 hour after the start of operation, Immediately, 6 and 24 hours after the completion of the operation

Method of measurement

Blood test

5

Description

Mean arterial pressure

Timepoint

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

Method of measurement

Gauge pressure

6

Description

Heart rate

Timepoint

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

Method of measurement

Electrocardiograph

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the case group, immediately after the induction, Dexmedetomidine with a bolus dose of (1 µg/kg) during 15 minutes and infusion with a dose of (0.5 µg/kg) will be injected until the end of surgery

Category

Treatment - Drugs

2

Description

Control group: In the control group, immediately after the induction, normal saline with a dose of (1 µg/kg) during 15 minutes and infusion with a dose of (0.5 µg/kg) will be injected 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

Shole Nesioonpur

Street address

Azadegan Ave., Imam Khomeini Hospital

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3222 2925

Email

drnesioon@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi, PhD

Street address

Deputy of Research, Ahvaz Jundishapur University of Medical Sciences, Golestan Blv.

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3373 8383

Email

info@ajums.ac.ir

Grant name**Grant code / Reference number**

33011369

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

Maryam Derakhshani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Azadegan Ave., Imam Khomeini Hospital

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61329235893

Email

derakhshani.m@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Shole Nesioonpour

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Azadegan Ave., Imam Khomeini Hospital

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61322235292

Email

nesioon@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Maryam Derakhshani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Azadegan Ave., Imam Khomeini Hospital

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61322235292

Email

derakhshani.m@ajums.ac.ir

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

Undecided - It is not yet known if there will be a plan to make this available

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