Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 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

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Iran (Islamic Republic of)

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
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Deputy of Research, Ahvaz Jundishapur University of Medical Sciences, Golestan Blv.
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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
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Person responsible for updating data

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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
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