

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison effect of subcutaneous Dexmedetomidine and subcutaneous Marcaine 0.5 % in hemodynamic changes and sedation during hernia surgery and management of pain after surgery

Protocol summary

Study aim

Aim of this study is evaluation effect of subcutaneous Dexmedetomidine and subcutaneous Marcaine 0.5 % in hemodynamic change and sedation during hernia surgery and management of pain after surgery.

Design

This study is clinical trial and double blind. 120 patients candidate hernia surgery in Valiasr hospital were divided in 3 groups by simple randomization. Groups are parallel.

Settings and conduct

120 patients candidate hernia surgery in Valiasr hospital. This study is double blind. Outcome assessor and analyzer don't aware from grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor. We record mean arterial blood pressure, heart rate, oxygen saturation, pain in each group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 years old to 65 years old, ASA Class I and II, candidates for hernia surgery, body mass index less than 30, no allergy to used drugs, lack of underlying illness, no smoking and addiction; Exclusion criteria: Dissatisfaction with participating in the study, refusal to undergo intracutaneous injection

Intervention groups

In the first group, we inject 5 milligram Marcaine 0.5% (Aboreihan Co) and 1 micro gram in kilogram Dexmedetomidin (PFIZER [America]) and distilled water. Final volume is 10 milliliter. In the second group, we inject 5 milligram Marcaine 0.5% (Aboreihan Co) and distilled water. Final volume is 10 milliliter. We inject 10 milliliter normal saline (Samen Co) in placebo group.

Main outcome variables

Mean arterial blood pressure, heart rate, oxygen saturation percentage, pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N99**

Registration date: **2019-03-20, 1397/12/29**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-20, 1397/12/29**

Update count: **0**

Registration date

2019-03-20, 1397/12/29

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

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	Comparison effect of subcutaneous Dexmedetomidine and subcutaneous Marcaine 0.5 % in hemodynamic changes and sedation during hernia surgery and management of pain after surgery
Public title	Comparison effect of subcutaneous Dexmedetomidine and subcutaneous Marcaine 0.5 % in hemodynamic changes and sedation during hernia surgery
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	18 years old to 65 years old ASA Class I and II Candidates for hernia surgery Body mass index less than 30 No allergy to used drugs Lack of underlying illness No smoking and addiction
Exclusion criteria:	Dissatisfaction with participating in the study Refusal to undergo intra cutaneous injection
Age	From 18 years old to 65 years old
Gender	Both
Phase	2-3
Groups that have been masked	• Participant • Outcome assessor • Data analyser
Sample size	Target sample size: 120
Randomization (investigator's opinion)	Randomized
Randomization description	Simple individual randomization with random number table in division of groups in two groups A and B. Randomization method: Simple randomization. Random unit: Individual. How to build sequences: First, we set the framework for our statistical society. We started from a table point in a row or column. Given the type of code in the row, we chose the same number of digits. After that, the numbers control the path. We noticed smaller numbers of the statistical community. We have to continue this work so that the number of samples is completed. Even numbers were used for intervention group and odd numbers were used for the control group. Allocation concealment: Numbered drug containers
Blinding (investigator's opinion)	Double blinded
Blinding description	This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B and C are available to analyzer and outcome assessor. The syringe containing the drugs are covered and labeled as A and B and C at

the discretion of anesthesiology residents.	
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethics committee of Arak University of Medical Sciences
Street address	Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak
City	Arak
Province	Markazi
Postal code	3848176941
Approval date	2018-08-19, 1397/05/28
Ethics committee reference number	IR.ARAKMU.REC.1397.131
Health conditions studied	
1	
Description of health condition studied	Hernia surgery
ICD-10 code	K40
ICD-10 code description	Inguinal hernia
Primary outcomes	
1	
Description	Mean arterial blood pressure
Timepoint	Every 5 minutes to the end of surgery and recovery
Method of measurement	Barometer
2	
Description	Heart rate
Timepoint	Every 5 minutes to the end of surgery and recovery
Method of measurement	Beat in minute

3

Description

Oxygen saturation

Timepoint

Every 5 minutes to the end of surgery and recovery

Method of measurement

Oximeter

4

Description

Pain

Timepoint

At recovery and at 2, 4, 6, 12, and 24 hours after surgery

Method of measurement

Questionnaire visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: We inject 5 milligram Marcaine 0.5% (Aboreihan Co) and 1 micro gram in kilogram Dexmedetomidin(PFIZER [America]) and distilled water.Final volume is 10 milliliter.

Category

Treatment - Drugs

2

Description

Intervention group 2: We inject 5 milligram Marcaine 0.5%(Aboreihan Co) and distilled water.Final volume is 10 milliliter.

Category

Treatment - Drugs

3

Description

Control group: We inject 10 milliliter normal saline(Samen Co) in placebo group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Dr Shirin Pazoki

Street address

Valiasr hospital, Valiasr squire

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandzadegan

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Hesamedin Modir

Position

Assistante professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is 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

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Shirin Pazuki

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

They have to write letters to the professors and the university

Comments