Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of pretreatment with Lidocaine , esmolol and ketorolac in pain control when injecting rocuronium

Protocol summary

Study aim
the main purpose of this study is to compare the effect of pretreatment with Lidocaine , Esmolol and Ketorolac in pain control when injecting rocuronium.

Design
Randomized double-blind trial with 4 parallel groups on 176 participants.

Settings and conduct
after receiving informed consent and recording participant's demographic information, 100 mg of normal saline was injected through each of the catheters inserted in the patients' arms in 10 minutes. then a tourniquet was placed in the middle of the arm and pumped u tp-o 250-350 mmHg pressure, to block venous drainage in both hands. then participants were assigned in 4 groups and drugs were administrated as explained.

Participants/Inclusion and exclusion criteria
inclusion criteria: Elective syrgery candidates undergoing general anesthesia aged 18 to 50 years old ASA class I or II Exclusion criteria: History of Thrombophlebitis, vascular disease, chronic pain, Diabetes History of burns, and tumors in the hand with the catheter History of addiction or any contraindications for the drugs used in the study Not consenting to participate in the study

Intervention groups
in 3 groups patients will receive a drug in one arm (10 mg Ketorolac in group K, 0.5 mg Esmolol in group S, 1 mg lidocaine in group L) and 2 mg normal saline in the other arm, and 2 mg normal saline in both arms in the control group (group P). after 2 minutes, the pressure is released and 3 mg/kg of Rocuronium 1% is injected simultaneously in both hands.

Main outcome variables
pain score according to the visual analog scale on injection and 1 minute after injection of Rocuronium; mean arterial blood pressure; arterial oxygen saturation; heart beat

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220719055498N1**
Registration date: **2022-08-10, 1401/05/19**
Registration timing: **prospective**

Last update: **2022-08-10, 1401/05/19**
Update count: **0**

Registration date
2022-08-10, 1401/05/19

Registrant information

Name
Nazanin Hassannejad

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3777 5374

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2023-03-21, 1402/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of pretreatment with Lidocaine , esmolol and ketorolac in pain control when injecting rocuronium

Public title
effect of Lidocaine , esmolol and ketorolac in pain control when injecting rocuronium
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Elective surgery candidates undergoing general anesthesia ASA class I and II
Exclusion criteria:
History of Thrombophlebitis, vascular disease, chronic pain, Diabetes History of burns, and tumors in the hand with the catheter History of addiction or any contraindications for the drugs used in the study Not consenting to participate in the study
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **176**
Randomization (investigator's opinion)
Randomized
Randomization description
In this clinical trial, as every group must have the same number of participants, block randomization method will be performed, and in order to avoid prediction of the last assignment in the block, block size will be chosen randomly (in 4s or 8s). If the randomized blocks all have the same size, there is a risk of predictability; for example in blocks of four with equal participants in control and intervention groups, with the assignment of the first 3 slots, the last one is easily predicted.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is double-blinded, hence the participants and the investigator responsible for gathering data are unaware of the drugs prescribed, and of the group assignments. we explain to the participants that they will be assigned to each of 4 groups and administrated a drug, labeled A, B, C or D on the syringe. only the Anesthetist is aware of the contents of each syringe and the participants and the investigator recording the data, will not have this information.
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
Arak university of Medical Sciences, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
848176941
Approval date
2022-06-26, 1401/04/05
Ethics committee reference number
IR.ARAKMU.REC.1401.094

Health conditions studied

1

Description of health condition studied
pain during Rocuronium injection in general anesthesia induction
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
visual analog scale pain scores
Timepoint
during and 1 minute after Rocuronium injection
Method of measurement
visual analog scale pain

Secondary outcomes

1

Description
mean arterial blood pressure
Timepoint
on entering the operation room, 5 minutes and ten minutes after injection of intervention drugs, at the time of induction and every 10 minutes after induction for 30 minutes
Method of measurement
Sphygmomanometer

2

Description
arterial oxygen saturation
Timepoint
on entering the operation room, 5 minutes and ten minutes after injection of intervention drugs, at the time of induction and every 10 minutes after induction for 30 minutes
Method of measurement
pulse oximetry

3

Description
Heart beat
Timepoint
on entering the operation room, 5 minutes and ten minutes after injection of intervention drugs, at the time of induction and every 10 minutes after induction for 30 minutes
Method of measurement
taking Radial pulse for 1 minute

Intervention groups

1

Description
Intervention group 1: group K, 10 mg ketorolac (Exir Iran pharmaceutical company) injection in 2 ml in the left arm and 2 mg of 0.9% Normal Saline simultaneously in the the right arm
Category
Treatment - Drugs

2

Description
Intervention group 2: group S, 0.5 mg/kg Esmolol (ORPHA-DEVEL pharmaceutical company) injection in 2 ml in the left arm and 2 mg of 0.9% Normal Saline simultaneously in the the right arm
Category
Treatment - Drugs

3

Description
Intervention group 3: group L, 1 mg/kg Lidocaine (Caspian Iran company) injection in 2 ml in the left arm and 2 mg of 0.9% Normal Saline simultaneously in the the right arm
Category
Treatment - Drugs

4

Description
Control group: group P, 2 ml of Normal Saline simultaneously in both arms
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Nazanin Hassannejad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Nazanin Hassannejad

Position
medical student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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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
No - There is not 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Participant data file (IPD), the data of the study participants is uploaded as an Excel file.The study protocol, informed consent form, clinical study report will be uploaded as a word file.

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
All researchers in the country can access the uploaded data.

Under which criteria data/document could be used
There are no special conditions for receiving data, and all researchers can get the uploaded information if the access to the system is open.

From where data/document is obtainable
All the information and documents of this study are placed in the research system of Arak University of Medical Sciences (Pajhuhan), whose address is http://vdresearch.arakmu.ac.ir/general /homePage.action and also after the completion of the study, all its information will be registered in the Irandoc system at the address https://irandoc.ac.ir/, applicants can refer to these addresses and enter the title study to access the desired data

What processes are involved for a request to access

data/document

The information requester first refers to the Arak medical sciences research system and by searching the name of the first author or the responsible author of the desired article, the related research file will be available, which is usually open to researchers in this system. Register the title of the article and get access to its documents.

Comments