Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparison of Succinylcholine and Rocuronium effects on the rate of emergence agitation when awakening in patients undergoing direct diagnostic laryngoscopy under general anesthesia

Protocol summary

Study aim

Determining the difference, severity and duration of agitation and the incidence of myalgia in patients undergoing rapid induction with Succinylcholine in general anesthesia compared with Rocuronium

Design

Forty-eight patients aged 20 to 50 years with a risk of ASA1-2 anesthesia will be randomly divided into two groups: succinylcholine and rocuronium. After surgery, the degree of agitation when waking up in both groups was recorded according to RIKER criteria. The results will be analyzed using SPSS software.

Settings and conduct

48 patients aged 20 to 50 years with risk of ASA1-2 anesthesia who will refer to Rasoul Akram Hospital for direct diagnostic laryngoscopic surgery and will be subjected to endotracheal intubation in two groups by rapid sequencing method. The first group for premedication Will receive 3 µg/kg fentanyl and 0.5 mg / kg lidocaine and will be induced with 1 mg/kg succinylcholine and 5 mg/kg Nesdonal. The second group for premedication will receive 3 µg/kg of fentanyl and 0.5 mg/kg of lidocaine and will be induced with 0.6 mg / kg rocuronium and 5 mg/kg Nesdonal. In the second group, patients receive rocuronium instead of succinylcholine.

Participants/Inclusion and exclusion criteria

- Patients aged 20 to 50 years at risk of ASA1-2 anesthesia will be referred for diagnostic laryngoscopy surgery. - Patients with a history of burns, peritonitis, hyperkalemia, renal and hepatic insufficiency, malignant hyperthermia, pseudocholinesterase deficiency, addiction, a history of benzodiazepines, and a history of psychiatric illness will not be included in the study.

Intervention groups

Patients are divided into two intervention groups receiving Succinylcholine and Rocuronium.

Main outcome variables

emergence agitation;Myalgia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210714051888N1**
Registration date: **2021-12-19, 1400/09/28**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-19, 1400/09/28**
Update count: **0**

Registration date

2021-12-19, 1400/09/28

Registrant information

Name

Sepideh Malekpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 1239

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mroozban@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A comparison of Succinylcholine and Rocuronium effects on the rate of emergence agitation when awakening in patients undergoing direct diagnostic laryngoscopy under general anesthesia

Public title
Succinylcholine and Rocuronium effects on the rate of emergence agitation

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients 20 to 50 years without a history of disease or with a controlled disease

Exclusion criteria:
The patients with a history of psychiatric illness The patients with a history of peritonitis The patients with a history of hyperkalemia The patients with a history of renal and hepatic failure The patients with a history of malignant hyperthermia and pseudocholinesterase deficiency The patients with a history of addiction The patients with a history of benzodiazepines The patients with a history of burns

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization in this clinical trial will be performed by blocking method. Accordingly, 8 blocks will be used, with 6 patients in each block (3 patients in the Saxinylcholine group and 3 patients in the Rocronium group). Randomization is done using random allocation softwares. In addition to simple randomization, these softwares are able to generate random sequences by blocking method. Random allocation concealment is used for hiding Which refers to the method used to execute a random sequence on the participants in the study, so that the assigned group is not known before the individual is assigned. Sequentially numbered opaque envelopes are also used, in which each of the random sequences created is recorded on a card and the cards are placed in the envelopes respectively. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the letter envelope lids are glued and placed in a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Patient information will be recorded in the data collection sheets by examination by a physician. The patient, the injector, and the person recording the results will be unaware of the type of drug. The person preparing the medicine will be different from the person who injected it.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, Hemmat Highway next to Milad Tower, Iran University of Medical Sciences, Tehran

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2020-11-30, 1399/09/10

Ethics committee reference number
IR.IUMS.FMD.REC.1399.565

Health conditions studied

1

Description of health condition studied
Diagnostic biopsy under direct laryngoscopy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Agitation

Timepoint

From the moment of closing the gas until 10 minutes after estubation for once

Method of measurement

Emergency agitation of patients from the moment of gas closure until 10 minutes after extubation will be performed according to the criteria of Ricker Sedation Agitation Scale.

2

Description

Myalgia

Timepoint

Myalgia pain scores will be recorded 1, 4, 8 and 24 hours after surgery

Method of measurement

Examination by a Physician

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: succinylcholine.The first group will receive 3 micrograms / kg of fentanyl and 0.5 mg / kg of lidocaine for premedication, and will be induced with 1 mg / kg of succinylcholine and 5 mg / kg of Nesdonal.The medications used will be common medications available in the operating room

Category

Treatment - Drugs

2

Description

Intervention group 2: Rocronium. The second group will receive 3 micrograms / kg of fentanyl and 0.5 mg / kg of lidocaine for premedication and will be induced with 0.6 mg / kg rocuronium and 5 mg / kg Nesdonal. Second, patients will receive rocuronium instead of succinylcholine.The medications used will be common medications available in the operating room

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Saeid Amniati

Street address

Hazrat Rasoul Akram Hospital, Niayesh St., Sattar Khan St., Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr. Hossein Kiwani

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Grant name

Grant code / Reference number

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

No

Title of funding source

دانشگاه علوم پزشکی ایران

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

Iran University of Medical Sciences

Full name of responsible person

Dr Saeid Amniati

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
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
All data can be shared after people are not identified.
When the data will become available and for how long
The data will be available 6 months after the results are published.
To whom data/document is available
Researchers from scientific and academic institutions can apply for the data.
Under which criteria data/document could be used
The data can only be used for scientific research by researchers in scientific and academic centers.
From where data/document is obtainable
Researchers can send their request via email to the project manager.
What processes are involved for a request to access data/document
Applications must be accompanied by a letter of introduction from the institution or university where the researcher is employed. The data will be provided to the researcher no later than two weeks after receiving the request.
Comments