Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effects of fentanyl versus remifentanyl pretreatment on the QTc interval in patients undergo rapid sequence intubation

Protocol summary

Study aim
Effects of fentanyl versus remifentanyl pretreatment on the QTc interval in patients undergo rapid sequence intubation

Design
Phase 2, randomized, parallel clinical trial. Randomization will be done by using a table of random numbers. Sample size will be 25 samples in each group.

Settings and conduct
Patients who need rapid sequence intubation admited in Imam Reza hospital, Tabriz, will be administered fentanyl and Novocain in control group and remifentanyl and lidocain in intervention group for prophylaxis. Sedation will be inducted by Etomidate and succinylcholine and laringoscopy and intubation will be done. ECG will be obtained prior to prophylaxis drugs injection, one minutes after medication injection and after laryngoscopy.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients older than 18 years old who need rapid sequence intubation for airway management. Patients with a history of cardiovascular disease, diabetes mellitus, chronic hypertension, intracranial injury, drug poisoning and chronic medication use will be excluded.

Intervention groups
Control group will be treated by 2 micg/Kg fentanyl and 1.5 Mg/Kg lidocaine five minutes before laryngoscopy. Three minutes after administration, sedation will be induced by 0.2 Mg/Kg etomidate and 1.5 Mg/Kg succinylcholine. Ninety seconds after induction laryngoscopy will be done. Intervention group will receive same drugs in same times and manner except fentanyl will be replaced by remifentanyl 1micg/Kg.

Main outcome variables
Corrected QT interval in 3 ECGs, longest QT interval, shortest QT interval and QT interval dispersion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090923002496N12**
Registration date: **2019-05-04, 1398/02/14**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-04, 1398/02/14**
Update count: **0**

Registration date
2019-05-04, 1398/02/14

Registrant information

Name
Hassan Soleimanpour

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 41 1329 1286

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soleimanpourh@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01

Expected recruitment end date
2019-10-23, 1398/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of fentanyl versus remifentanyl pretreatment on the QTc interval in patients undergo rapid sequence intubation

Public title
Effects of fentanyl versus remifentanyl pretreatment on the QTc interval in patients undergo rapid sequence intubation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients need airway management by rapid sequence intubation/induction Age over 18 years
Exclusion criteria:
cardiovascular disease diabetes chronic hypertension hypersensitivity to fentanyl or remifentanyl intracranial injury drug poisoning
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **25**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, subjects will be divided in control and intervention groups individually by using a simple randomization method by table of random numbers.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethic committee of Research Vice chancellor of Tabriz University of Medical Sciences
Street address
Research Vice chancellor of Tabriz University of Medical Sciences ,Tabriz University of Medical Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN
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Tabriz
Province
East Azarbaijan
Postal code
51664
Approval date
2019-02-04, 1397/11/15
Ethics committee reference number
IR.TBZMED.REC.1397.921

Health conditions studied

1

Description of health condition studied
Rapid sequence intubation/induction
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
corrected QT interval
Timepoint
Before administration of fentanyl or remifentanyl, 1 minute after administration and after laringoscory
Method of measurement
ECG

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In pretreatment Phase of RSI a single dose of 1 micg/Kg of remifentanyl (Hamlen- Germany) will be administrated intravenously.
Category
Treatment - Drugs

2

Description
Control group: In pre-treatment phase of RSI a single dose of 2 micg/Kg of fentanyl will be injected intravenously. We will use the fentanyl made by Aburaihan pharmaceutical Co.-Iran.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital

Full name of responsible person
Dr.Hassan Soleimanpour
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Emergency Medicine Department, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Abolghasem Jouyban
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Research Vice chancellor of Tabriz University of Medical Sciences ,Tabriz University of Medical Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN.
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Hassan Soleimanpour
Position
professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Professor

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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 collected de identified IPD.

When the data will become available and for how long

Data will be available in september 2020.

To whom data/document is available

Data will be available for all interested researchers.

Under which criteria data/document could be used

Data will be available for use in other studies. researchers can ask for data of this study by sending email to dr. Hassan Soleimanpour.

From where data/document is obtainable

Dr. Hassan Soleinampour soleimanpourh@tbzmed.ac.ir

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

In two weeks after sending data request email, they can receive data.

Comments