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 admitted 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
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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
A 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
City
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 laringoscopy

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

Street address
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
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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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Hassan Soleimanpour

Position
Professor

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Hassan Soleimanpour

Position
Professor

Personal information

Title
Specialist

Other areas of specialty/work
Anesthesiology

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Anesthesiology

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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

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**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 Soleimanpour 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**