

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 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 induced by Etomidate and succinylcholine and laryngoscopy 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)

Phone

+98 41 1329 1286

Email address

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

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

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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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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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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 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