

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison Effect of Fentanyl, Sufentanil and Alfentanil on Hemodynamic at Rapid Sequence Intubation in the Emergency Department

Protocol summary

Summary

1) Objectives: This research was accomplished with the purpose of effect of different opioids on traumatic patients' hemodynamic at rapid sequence intubation. 2) Design: 90 traumatic patients aged 18-65 with ASA class I-II who need rapid sequence intubation at emergency department. 3) Setting and conduct: Patients are divided in three groups randomly. Prior to intubation, patients will undergo cardiac monitoring using SAADAT instrument. Heart rate and arterial oxygen saturation will be checked using the same instrument. End-tidal CO₂, cardiac output and cardiac index will be measured using NICO instrument. Five minutes after register these data intubation will be done and 3, 5 and 10 minutes after intubation the monitoring data will also be registered. 4) Participants including major eligibility criteria: inclusion criteria: all traumatic patients with normal blood pressure and require intubation. Exclusion criteria include crash intubation. 5) Intervention: Type of used opioids in three group are different. In group one fentanyl, group two alfentanil and group three sufentanil are used as opioid. 6) Main outcome measures variables: The changes observed in these variables will be compared between three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012101011067N1**

Registration date: **2013-05-12, 1392/02/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-05-12, 1392/02/22

Registrant information

Name

Mahboub Pouraghaei

Name of organization / entity

Tabriz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 2078

Email address

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-05-05, 1392/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Effect of Fentanyl, Sufentanil and Alfentanil on Hemodynamic at Rapid Sequence Intubation in the Emergency Department

Public title

comparison of three drugs to prevent hemodynamic response of orotracheal intubation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria include all traumatic patients with normal blood pressure that require intubation in the Emergency Department of Imam Reza (AS) Medical

Research and Training Hospital. Exclusion criteria:Crush intubation, Asthma, Chronic Obstructive Pulmonary Disease, Porphyry, Allergy to lidocaine,difficult intubation based on physician's clinical judgment.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization was performed by providing the intubating physician, without informing him about the name of the medication, the different opiates labeled 1, 2 and 3 which were placed in the syringes containing similar amount of medication in each milliliter. When the patient entered the room, a ball was drawn from a bag containing 90 balls (30 balls labeled as 1, 30 as 2 and 30 as 3). Later, based on the number of the ball, the syringe with the similar number was used for the patient throughout the intubation. Neither the patient nor the physician was aware of the name of the opiate used in the intubation as the syringes were placed on the intubation tray by the project executor.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tabriz University of Medical Sciences

Street address

Golgasht Street, Tabriz University of Medical Sciences

City

Tabriz

Postal code

Approval date

2011-06-12, 1390/03/22

Ethics committee reference number

5/4/2705

Health conditions studied

1

Description of health condition studied

accidents

ICD-10 code

V01-X59

ICD-10 code description

Accidents

Primary outcomes

1

Description

Heart Rate

Timepoint

5 minute before intubation, 3 minute after intubation, 5 minute after intubation, 10 minute after intubation and

Method of measurement

SAADAT Monitoring Device (Model Number: Novin S1800, Pooyandegan Rah Saadat Incorporation, Tehran, Iran)

2

Description

Blood Pressure

Timepoint

5 minute before intubation, 3 minute after intubation, 5 minute after intubation, 10 minute after intubation and

Method of measurement

SAADAT Monitoring Device (Model Number: Novin S1800, Pooyandegan Rah Saadat Incorporation, Tehran, Iran)

3

Description

Cardiac Output

Timepoint

5 minute before intubation, 3 minute after intubation, 5 minute after intubation, 10 minute after intubation and

Method of measurement

NICO Monitoring Device (Model Number:7300, Novamatrix Incorporation, Wallingford, United States of America)

4

Description

Pressure of End Tidal Carbon Dioxide

Timepoint

5 minute before intubation, 3 minute after intubation, 5 minute after intubation, 10 minute after intubation and

Method of measurement

NICO Monitoring Device (Model Number:7300, Novamatrix Incorporation, Wallingford, United States of America)

5

Description

Arterial Oxygen Saturation

Timepoint

5 minute before intubation, 3 minute after intubation, 5 minute after intubation, 10 minute after intubation and

Method of measurement

SAADAT Monitoring Device (Model Number: Novin S1800, Pooyandegan Rah Saadat Corporation, Tehran, Iran)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: 30 accidental patients with normal blood pressure that will require intubation with rapid sequence method, alfentanil, single dose intravenous administration 20 micrograms per kilogram (1 cc :500micrograms, Janssen Pharmaceutical Company, Beerse, Belgium) has been used for intubation.

Category

Treatment - Drugs

2**Description**

Intervention group 1: 30 accidental patients with normal blood pressure that will require intubation with rapid sequence method, sufentanil, single dose intravenous administration 0.2 micrograms per kilogram (1 cc :5 micrograms, Mylan Pharmaceutical Company, Saint Priest, France) has been used for intubation.

Category

Treatment - Drugs

3**Description**

Control group: 30 accidental patients with normal blood pressure that will require intubation with rapid sequence method, fentanyl, single dose intravenous administration 2 micrograms per kilogram (1 cc :50 micrograms, Mylan Pharmaceutical Company, Saint Priest, France) has been used for intubation.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza (AS) Medical Research and Training Hospital, Tabriz

Full name of responsible person

Mahboob Pouraghaei

Street address

Golgasht Street, Imam Reza (AS) Medical Research and Training Hospital, Emergency Department

City

Tabriz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Vice-Chancellor of Tabriz University of Medical Sciences

Full name of responsible person

Seyed Kazem Shakouri

Street address

Golgasht Street, Tabriz University of Medical Sciences

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Vice-Chancellor of Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mahboob Pouraghaei

Position

Assistant Professor / Emergency Medicine Specialist

Other areas of specialty/work**Street address**

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Full name of responsible person

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Position

Assistant Professor / Emergency Medicine Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty