

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparative study of the early intubation impact with conventional therapy, complications and outcome in patients with severe chest injury

Protocol summary

Study aim

Comparison of the Effect of Early intubation with Routine Therapy

Design

Clinical trials with control group, with parallel groups, without blindness, randomized

Settings and conduct

Sixty patients who have been referred to Alzahra and Kashani hospitals with Multiple Trauma during the years 1395 and 1396 are enrolled in the study. Patients are visited by an emergency specialist when they arrive at a hospital. A radiologic picture of the chest is performed by the portable patient and by the chest radiography, the patient's score is calculated using the Thoracic Trauma Score table, and if the score is greater than or equal to 5, will randomly enter into an intervention or control group. Intubation of patients in the Rapid sequence intubation and classical intubation is performed in the intervention group. In the control group, necessary routine supportive measures will be performed. Then, in the test group, after one day (24 hours) intubation, if necessary the patient will be extubated, there will be no contraindications. Became Conditions will be the same for all patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All individuals with multiple trauma; People over 18 years old; Exclusion criteria: Patients with severe head trauma with GCS less than or equal to 8; Patients with respiratory distress whit respiratory rate less than 9 or more than 30;

Intervention groups

For intubation of patients in the test group, a Rapid sequencing intubation and classical intubation will be performe, and in the control group, necessary routine supportive measures will be performed. Then, patients in the test group after one day (24 hours) of intubation will be extubated in the absence of the necessary contraindications.

Main outcome variables

PH, Hco3, Pco2, PaO2, Systolic blood and Diastolic blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N31**

Registration date: **2019-07-06, 1398/04/15**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-06, 1398/04/15**

Update count: **0**

Registration date

2019-07-06, 1398/04/15

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 31 3629 1510

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative study of the early intubation impact with conventional therapy, complications and outcome in patients with severe chest injury

Public title
The effect of early intubation in patients with severe chest pains

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All individuals with multiple trauma who receive more than or equal to 5 points from the TTS rating system
People over 18 years old
Exclusion criteria:
Patients with severe head trauma with GCS less than or equal to 8
Patients with respiratory distress with respiratory rate less than 9 or more than 30
Airway obstruction
Severe Hypoxia
Cardiac arrest
Severe hemorrhagic shock
Burn more than 40%
Severe Facial Burn

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Randomization block, randomization unit: Individual, Random layer: not done
Randomization, tool: Random sequence generation software (Excel), How to create random sequence: Using random blocks, each block contains 4 people And assign a number from 1 to 6 to each block

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
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan University of medical sciences, Isfahan, Iran.
City
Isfahan
Province
Isfahan
Postal code
7346181746
Approval date
2017-03-11, 1395/12/21
Ethics committee reference number
IR.MUI.MED.REC.1395.804

Health conditions studied

1

Description of health condition studied
Fracture of rib(s), sternum and thoracic spine
ICD-10 code
S22
ICD-10 code description
Fracture of rib(s), sternum and thoracic spine

Primary outcomes

1

Description
Systolic blood and Diastolic blood pressure
Timepoint
Every three hours until the first 6 hours of admission to the emergency room, then every 6 hours to 18 hours, then daily until discharge from the hospital will be launched.
Method of measurement
Using sphygmomanometer

2

Description
PaO2
Timepoint
Every three hours until the first 6 hours of admission to the emergency room, then every 6 hours to 18 hours, then daily until discharge from the hospital will be launched.
Method of measurement
pulse oximeter

3

Description
Pco2
Timepoint
Every three hours until the first 6 hours of admission to the emergency room, then every 6 hours to 18 hours,

then daily until discharge from the hospital will be launched.

Method of measurement

laboratory test for measuring blood acidity

4**Description**

Hco3

Timepoint

Every three hours until the first 6 hours of admission to the emergency room, then every 6 hours to 18 hours, then daily until discharge from the hospital will be launched.

Method of measurement

laboratory test for measuring blood acidity

5**Description**

PH

Timepoint

Every three hours until the first 6 hours of admission to the emergency room, then every 6 hours to 18 hours, then daily until discharge from the hospital will be launched.

Method of measurement

laboratory test for measuring blood acidity

Secondary outcomes

empty

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

Intervention group: Intubation of patients in the Rapid sequence intubation and classical intubation is performed in the intervention group

Category

Treatment - Devices

2**Description**

Control group: necessary routine supportive measures will be performed

Category

N/A

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

Alzahra hospital

Full name of responsible person

Amir Bahador Boromand

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Alzahra Hospital, Sofe street, Isfahan, Iran

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Web page address

http://alzahra.mui.ac.ir

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

Esfahan University of Medical Sciences

Full name of responsible person

Dr Shaghayegh Haghjoo Javanmard

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Isfahan University of Medical Sciences, Hezar jareeb street, Isfahan, 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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Dr Mohammad Nasr Esfahani

Position

General Surgeon
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Web page address

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 will be shared

When the data will become available and for how long

Immediately after the publication of the article

To whom data/document is available

People who need this information

Under which criteria data/document could be used

All uses are allowed

From where data/document is obtainable

please contact to this Email address:

M_nasr@med.mui.ac.ir

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

After sending the request, the requested information will be provided to you within a short period of time.

Comments