

# 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)

##### Phone

+98 31 3629 1510

##### Email address

mehrabi@mui.ac.ir

##### 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

**Street address**

Alzahra Hospital, Sofe street, Isfahan, Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3620 2020

**Email**

alzahra@mui.ac.ir

**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

**Street address**

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

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Phone**

+98 31 3792 3060

**Email**

sh\_haghjoo@med.mui.ac.ir

**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  
**Street address**  
Dermatology group, Alzahra hospital, Sofe street,  
Isfahan  
**City**  
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**Province**  
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8174675731  
**Phone**  
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**Fax**  
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**Email**  
M\_nasr@med.mui.ac.ir  
**Web page address**

## Person responsible for scientific 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  
**Street address**  
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## Person responsible for updating data

### 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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**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