

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The comparative effectiveness of airway management in pre-hospital

Protocol summary

Summary

Quick stabilization of airway in damaged victims is a priority for pre-hospital care. The aim of this study was to compare the effectiveness of laryngeal mask, oral pharyngeal and tracheal tube in the pre-hospital situation. Inclusion criteria: Patient's GCS less than 9 and age greater than 18 years. Exclusion criteria: Impossibility of measuring hemodynamic responses before and after intervention. The study population: patients for whom intubation is not possible for any reason. They are randomly placed into groups: oral pharyngeal and laryngeal masks. Hemodynamic parameters are measured maximum after 10 minutes of the intervention. Sampling: 81 patients in 3 groups of people: Laryngeal mask, end tracheal tubes, oral and pharyngeal.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012092310910N1**

Registration date: **2012-11-21, 1391/09/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-11-21, 1391/09/01

Registrant information

Name

Jalal Borna

Name of organization / entity

Gonabad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 53 3722 3028

Email address

jalal.borna@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Personal and Research Budget of Gonabad University of Medical Sciences

Expected recruitment start date

2012-12-31, 1391/10/11

Expected recruitment end date

2013-07-15, 1392/04/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparative effectiveness of airway management in pre-hospital

Public title

Effectiveness of laryngeal mask in airway management

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Patient GCS less than 9; age greater than 18 years; without damage to the jaw and mouth; absence of pregnancy. Exclusion criteria: Impossibility of measuring hemodynamic responses before and after intervention.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

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 committe of Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences

City

Gonabad

Postal code

9691793718

Approval date

2012-08-08, 1391/05/18

Ethics committee reference number

91/3/1/الف/ك

Health conditions studied

1

Description of health condition studied

Victims patients requiring resuscitation

ICD-10 code

S06.2

ICD-10 code description

Diffuse brain injury

2

Description of health condition studied

cardiac patients requiring resuscitation

ICD-10 code

I46.9

ICD-10 code description

Cardiac arrest, unspecified

Primary outcomes

1

Description

Measurement of hemodynamic parameters

Timepoint

Twice, before and after insertion of airway devices

Method of measurement

Blood pressure control with pressure gauge, heart rate and blood oxygen with pulse oximetry

Secondary outcomes

1

Description

Duration of intervention

Timepoint

Twice, before and after intervention

Method of measurement

Timer

2

Description

Number of attempts

Timepoint

Before insertion

Method of measurement

questionnaire

3

Description

Necessary to use the laryngoscope

Timepoint

before insertion

Method of measurement

Questionnaire

4

Description

Technicians Satisfaction

Timepoint

after intervention

Method of measurement

questionnaire

5

Description

patient Coughing

Timepoint

after intervention

Method of measurement

questionnaire

6

Description

Patient gagging

Timepoint

before intervention

Method of measurement

questionnaire

7

Description

Moving the patient's head

Timepoint

before intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Effect of tracheal tube

Category

Prevention

2

Description

Effect of oropharyngeal air way

Category

Prevention

3

Description

Effect of Laryngeal Mask air way

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Disaster and Emergency Medical Management Center

Full name of responsible person

Dr. Javad Bazeli

Street address

Next to the Bohlol Hospital

City

Gonabad

2

Recruitment center

Name of recruitment center

Disaster and Emergency Medical Management Center

Full name of responsible person

Dr. Hamed Jafarzade

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Ali Ekrami

Street address

Gonabad University of Medical Sciences

City

Gonabad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gonabad 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

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Jalal Borna

Position

MSc. Student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Shahla Khosravan

Position

PhD in Nursing Education

Other areas of specialty/work

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Fax**Email****Web page address****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