

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

comparison of the accuracy value of color Doppler epigastric ultrasound and superficial probe Suprasternal Notch sonography in comparison with standard capnography method in diagnose of tracheal tube location after intubation

Protocol summary

Study aim

Diagnostic value of color Doppler epigastric sonography and sonography with surface probe in suprasternal notch compared to standard capnography method in Detection of endotracheal tube location Whereas the findings of this study indicate the high accuracy of sonography to detect the exact location of the endotracheal tube after intubation, This method can be used instead of capnography

Design

Diagnostic clinical trial-No control group-Double blind

Settings and conduct

This study will be conducted in Alzahra and Kashani teaching hospitals in Isfahan. Patients will be selected in an easily accessible non-random way. intubation will be performed by emergency medicine assistants And immediately afterwards, Placed by the assistant in charge of implementing the Color Doppler ultrasound probe plan on Epigastric. By changing the blue and red due to airflow presence or absence of a tube in the esophagus is determined surface probe is also transversely in front of the neck in the suprasternal notch and presence or absence of a tube in the trachea is determined At the same time, the nurse determines the tube location by capnography. Emergency Medicine Assistant Unaware of Capnographic Outcome and Nurse Unaware of Ultrasound Outcome. Ultrasound and capnography results are compared by the assistant in charge with chest x-ray

Participants/Inclusion and exclusion criteria

1-Age over 18 years 2-Emergency hospitalization 3-Requires intubation by RSI 4-Absence of abdominal and thoracic trauma 5- hemodynamic changes 6- unable to supine position

Intervention groups

this is a diagnostic study, Diagnostic value of ultrasound

to Locate the endotracheal tube In patients requiring intubation Compared to the gold standard (capnography).that done in patients who need intubation in emergency department and meet the inclusion criteria

Main outcome variables

More precise diagnosis of endotracheal tube placement

General information

Reason for update

Acronym

RSI

IRCT registration information

IRCT registration number: **IRCT20161004030149N2**

Registration date: **2019-12-23, 1398/10/02**

Registration timing: **prospective**

Last update: **2019-12-23, 1398/10/02**

Update count: **0**

Registration date

2019-12-23, 1398/10/02

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 317726332

Email address

smajidinejad@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01
Expected recruitment end date
 2020-09-21, 1399/06/31
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 comparison of the accuracy value of color Doppler
 epigastric ultrasound and superficial probe Suprasternal
 Natch sonography in comparison with standard
 capnography method in diagnose of tracheal tube
 location after intubation

Public title
 sonography in tracheal tube location

Purpose
 Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria:
 Emergency hospitalization Requires intubation by RSI
 method Absence of abdominal and thoracic trauma
Exclusion criteria:
 occurrence of hemodynamic changes unable to supine
 position

Age
 From **18 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
 Target sample size: **104**

Randomization (investigator's opinion)
 N/A

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description
 In this study, the patient, which is intubated in the
 emergency room, location of tracheal tube determined
 by the emergency medicine assistant immediately with
 ultrasound device, and the emergency nurse
 simultaneously determines the accuracy of the
 endotracheal tube with capnography so that the two
 results do not match each other. They are informed and
 the information is given to the analyzer

Placebo
 Not used

Assignment
 Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of isfahan university of medical
 science

Street address

isfahan university of medical science-hezar jerib blvd-
 isfahan

City

isfahan

Province

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶

Approval date

2019-09-29, 1398/07/07

Ethics committee reference number

IR.MUI.MED.REC.1398.246

Health conditions studied

1

Description of health condition studied

intubated patient

ICD-10 code

ICD-10 code description

d

Primary outcomes

1

Description

more precise diagnosis of endotracheal tube
 placementwith

Timepoint

Immediately after endotracheal intubation

Method of measurement

Compare to the gold standard that is capnography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

alzahra hospital

Full name of responsible person

saeed majidinejad

Street address

Emergency Department - Alzahra Hospital- Sofeh Ave
- Isfahan

City

isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2085

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

shaghayegh haghjooy javanmard

Street address

Hezar Jarib Street, Isfahan University of Medical
Sciences, Staff Building No. 5 - Vice chancellor for
research

City

isfahan

Province

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶

Phone

+98 31 3668 8138

Email

research@mui.ac.ir

Web page address

<https://research.mui.ac.ir/fa/contact>

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

saeed majidinejad

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Emergency department-Al-Zahra Hospital-Shohadaye
sofe Blvd-Isfahan

City

isfahan

Province

Isfahan

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

saeedmajidinejad

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

saeed majidinejad

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Web page address

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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

No - There is not 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 Shared after unidentifiable people

When the data will become available and for how long

6Months after publishing the results

To whom data/document is available

Only researchers working in academic institutions

Under which criteria data/document could be used

There are no other limitation

From where data/document is obtainable

Request email saeedmajidinejad@yahoo.com

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

They will receive the files and documentation within 15 days

Comments