

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of Neck Extension Versus Ultrasound Guided Distance Measured from Skin to Epiglottis (DSE) as Sole Predictors of Difficult Intubation

Protocol summary

Study aim

The objective of this study is to compare the conventional measurement of neck extension versus ultrasound guided distance measured from skin to epiglottis (DSE) as sole predictors in determining difficult airway and laryngoscopy.

Design

150 patients (minimum sample size 139 as per WHO calculator) were included in the study as per the inclusion criteria furnished. The method of sampling was non-probability consecutive via lottery method.

Settings and conduct

Maximum angle for neck extension in was measured with the patient sitting while keeping the head erect with mouth wide open and then asked to extend the head maximally while the anesthetist measured the angle traversed by the occlusal surface of the upper teeth. In Group E, linear probe using ultrasound guidance was used to measure the distance from skin to epiglottis in the sniffing position with the patient lying supine. To remove bias, the anesthetist performing pre-operative airway assessment were different to those confirming through Cormack Lehane scoring.

Participants/Inclusion and exclusion criteria

Inclusion criteria included all ASA I and II patients aged 20-40 years presenting to the anesthesia department after pre-anesthesia assessment for subsequent elective surgeries under general anesthesia. Exclusion criteria excluded patients with patients with a history of burns or trauma to the airways, patient with a history of tracheostomy or lower airway surgeries and patients unwilling to be included in the study.

Intervention groups

All the patients included in the study were divided into two groups, Group N, undergoing neck extension as sole predictor and Group E, using DSE by USG as a sole predictor for difficult airway.

Main outcome variables

Comparison of sensitivity and specificity showed a sensitivity of 76.9% in Group N versus 88.4% in Group E (DSE). Specificity showed 69.4% in Group N versus 87.5% in Group E.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230809059095N2**

Registration date: **2023-09-12, 1402/06/21**

Registration timing: **retrospective**

Last update: **2023-09-12, 1402/06/21**

Update count: **0**

Registration date

2023-09-12, 1402/06/21

Registrant information

Name

Hassan Minhas

Name of organization / entity

Combined Military Hospital, Rawalpindi, Pakistan

Country

Pakistan

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+92 345 5264734

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-01, 1400/10/11

Expected recruitment end date

2022-06-30, 1401/04/09
Actual recruitment start date
 2022-01-01, 1400/10/11
Actual recruitment end date
 2022-06-30, 1401/04/09
Trial completion date
 2022-06-30, 1401/04/09

Scientific title
 Comparison of Neck Extension Versus Ultrasound Guided Distance Measured from Skin to Epiglottis (DSE) as Sole Predictors of Difficult Intubation

Public title
 Sole Predictors of Difficult Intubation - Neck Extension Vs DSE

Purpose
 Screening

Inclusion/Exclusion criteria
Inclusion criteria:
 ASA I and II patients aged 20-40 yrs Elective Surgery Surgery under General Anesthesia
Exclusion criteria:
 History of Burns and Trauma to airway Tracheostomy Previous lower airway surgery Unwilling

Age
 From **20 years** old to **40 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
 Target sample size: **139**
 Actual sample size reached: **150**

Randomization (investigator's opinion)
 Randomized

Randomization description
 The method of sampling was non-probability consecutive via lottery method.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 To remove bias, the anesthetist performing pre-operative airway assessment were different to those confirming through Cormack Lehane scoring during intubation

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Combined Military Hospital, Rawalpindi, Pakistan

Street address

CMH Road

City

Rawalpindi

Postal code

46000

Approval date

2021-12-15, 1400/09/24

Ethics committee reference number

431/12/21

Health conditions studied

1

Description of health condition studied

Screening for Difficult Intubation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

ultrasound guided distance measured from skin to epiglottis is superior to conventional neck extension when used as sole agents to diagnose difficult airwayin suspected patients.

Timepoint

On intubation

Method of measurement

Visibility on laryngoscopy

Secondary outcomes

empty

Intervention groups

1

Description

Comparison group 1: undergoing neck extension as sole predictor

Category

Early detection

2

Description

Comparison group 2: using DSE by USG as a sole predictor for difficulty airway

Category

Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center

Combined Military Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Armed Forces Post Graduate Medical Institute

Full name of responsible person

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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

Armed Forces Post Graduate Medical Institute

Proportion provided by this source

100

Public or private sector

Private

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

Armed Forces Post Graduate Medical Institute

Full name of responsible person

Hassan Nasir Minhas

Position

Registrar

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Full name of responsible person

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Person responsible for updating data

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Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Sharing plan**Deidentified Individual Participant Data Set (IPD)**