

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

A comparison of prevalence of post-extubation stridor in cuffed and uncuffed endotracheal tubes in 4-6 years old children

Protocol summary

Summary

For more than 50 years, uncuffed tracheal tubes (tt) have been the gold standard for intubation in children under the age of 8 yr, however recently has been interest in the use of cuffed tubes in pediatric practice. The aim of this study was to compare post-extubation stridor and hemodynamic changes when using cuffed versus uncuffed tubes in children 4-6 years old. Inclusion criteria are: the age 4-6 year old and intubation for elective orthopedic surgery, or abdomen surgery. Exclusion criteria are parents discontent, coexistent disease and surgery's longer than 2 hours. 200 patients age from 4-6 yr are assigned randomly to receive either a cuffed tube or an uncuffed tube. End points are incidence of post-extubation stridor immediately after and 5 minutes after extubation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205269868N1**

Registration date: **2012-07-09, 1391/04/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-09, 1391/04/19

Registrant information

Name

Mohammad Mehdi Zhand

Name of organization / entity

Medical Science University Ahwaz

Country

Iran (Islamic Republic of)

Phone

+98 21 8898 2226

Email address

zhand.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

University Of Medical Sciences Ahwaz Jondi Shapur

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2013-02-18, 1391/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of prevalence of post-extubation stridor in cuffed and uncuffed endotracheal tubes in 4-6 years old children

Public title

A comparison of prevalence of post-extubation stridor in cuffed and uncuffed endotracheal tubes in 4-6 years old children

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria : Age 4-6: intubation for orthopedic or abdominal surgeries :Tracheal at the end of surgeries :Extubation at the end of surgeries in operating room :Supin position surgeries :Elective surgeries :asa class I .
Exclusion criteria : Parents discontent :Air way infection :Difficult intubation :Full stomach :Aspiration or regurgitation risk :Larynx or air way surgery :Lung disease. :Mechanical ventilation after surgery :Surgery more than 2 hours

Age

From **4 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

University Of Medical Scinces Ahwaz Jondi Shapur

Street address

Ahwaz, Golstan

City

Ahwaz

Postal code**Approval date**

2011-09-23, 1390/07/01

Ethics committee reference number

Eth242

Health conditions studied**1****Description of health condition studied**

Stridor

ICD-10 code

Jo4.0

ICD-10 code description

Laryngitis

Primary outcomes**1****Description**

Stridor

Timepoint

0-5minute

Method of measurement

Observation

Secondary outcomes**1****Description**

Respiratory

Timepoint

0-5 minute

Method of measurement

Count

2**Description**

Spo2(oxygen percent saturation)

Timepoint

0-5 minute

Method of measurement

Percent

3**Description**

Blood pressure

Timepoint

0-5 minute

Method of measurement

Mmhg

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

using uncuffed tubes after induction of general anesthesia in second group.

Category

Other

2**Description**

Using cuffed tubes after induction of general anesthesia in on group.

Category

Other

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

Emam khomeyni hospital , ahwaz

Full name of responsible person

Dr.fateme javaher foroosh

Street address

Avi. 24 metre

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University Of Medical Sciencec Ahwaz Jondi shapur

Full name of responsible person

Dr.mostafa fegghi

Street address

Golstan

City

Ahwaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University Of Medical Sciencec Ahwaz Jondi shapur

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

University Of Medical Sciences Ahwaz Jondi Shapur

Full name of responsible person

Dr.fateme javaher foroosh zadeh

Position

Anesthesiologist(m.D)/assistant professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Other areas of specialty/work

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golestan

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ahwaz

Postal code

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+98 61 1333 7681

Fax

Email

f-javaherforoosh@

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