Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparison of prevalence of post-extubation strider 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 intrest in the use of cuffed tubes in pediatric practice. The aim of this study was to compare post-extubation stridor and hemo dynamic changes when using cuffed versus uncuffed tubes in children 4-6years old. In clusion criteria are: the age 4-6 year old and intubation for elective ortheopedic surgery ,or abdomen surgery. Exclusion criteria are parents discontent,coexist disease and surgery's langer than 2 hours. 200 patients age from 4-6 yr are assigned randomly to receive either a cuffed tube or an un cuffed tube . End points are incidence of post-extubation stridor immidiatly 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 Sience University Ahwaz

Country

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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 strider in cuffed and uncuffed endotracheal tubes in 4-6 years old children

Public title

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

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion craiteria : Age 4-6؛ intubion 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 classI . Exclusioncraiteria : Parets discontent ؛Air way infection ؛Difficult intubation ؛Full stomach ؛Asriration or regorgitation risk ؛Larynx or air way surgery ؛Lung disease. ؛Mecanical ventilation after surgery ؛Surgerymorethan2houres

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 secend 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 feghhi
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
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Person responsible for updating data

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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