Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the results of reducing the time of the first tracheostomy tube change from seven days to three days in one-day to fifteen year old children

Protocol summary

Study aim

Determining the results of reducing the time of the first tracheostomy tube exchange from 7 days to 3 days in children from one day to 15 years old

Design

A clinical trial with a control group, with parallel groups, a blind strain, randomized by block randomization method, on 40 patients. A table of random numbers was used for randomization.

Settings and conduct

After performing a tracheostomy in the operating room of the Children's Medical Center (subcutaneous injection of lidocaine-epinephrine solution 1/100000 1cm below the cricoid; transverse skin incision in the midline, longitudinal dissection of the strap muscles in the midline; longitudinal incision between the 2-4 rings of the trachea; stay a suture is applied and the single cannula tube is fixed with two bands) according to the randomized block table, the patients are divided into two groups, control and intervention, and the parents are unaware of which group is intervention or control. All post-operative care in two groups It is done in the same way.

Participants/Inclusion and exclusion criteria

Children aged one day to 15 years who underwent tracheostomy at the Children's Medical Center in the ENT Service and their parents gave written consent to their children's participation in this study.

Intervention groups

The tracheostomy tube of the control group was changed on the 7th day after the operation and the intervention group on the 3rd day.

Main outcome variables

Possible common complications related to tracheostomy & its change; The effects of reducing the time of changing the first tracheostomy tube on the length of stay in ICU & hospital and the duration of receiving sedatives after tracheostomy; The relationship between common complications of tracheostomy & the day of change based on the indication of tracheostomy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231009059672N1**
Registration date: **2023-10-19, 1402/07/27**
Registration timing: **retrospective**

Last update: **2023-10-19, 1402/07/27**
Update count: **0**

Registration date

2023-10-19, 1402/07/27

Registrant information

Name

Zeynab Agahi Keshe

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-22, 1400/06/31

Expected recruitment end date

2023-03-18, 1401/12/27

Actual recruitment start date

2022-08-17, 1401/05/26

Actual recruitment end date
2023-09-22, 1402/06/31
Trial completion date
empty

Scientific title
Evaluation of the results of reducing the time of the first tracheostomy tube change from seven days to three days in one-day to fifteen year old children

Public title
Evaluation of the results of reducing the time of the first tracheostomy tube change in children
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age between one day and 15 years Perform tracheostomy by ENT service Presence of tracheostomy indication Tracheostomy in children's medical center Consent of the patient's parents to participate in the study
Exclusion criteria:
Lack of parental consent Tracheostomy performed by a service other than ENT Performing tracheostomy outside the children's medical center
Age
From **1 day** old to **15 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **40**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to maintain the balance between the two groups, the block randomization method will be used. So that 10 blocks of four people will be formed and 5 blocks will be assigned to each studied group. Also, a table of random numbers will be used to assign people to each block.
Blinding (investigator's opinion)
Single blinded
Blinding description
Considering that the patient's parents do not know the time difference of the first tracheostomy tube change and the doctor is aware of this issue, this study is a blind strain.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Children's Medical Center/Tehran University of Medical Sciences
Street address
Children's Medical Center, No 62, Dr Gharib St, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1419733151
Approval date
2022-08-17, 1401/05/26
Ethics committee reference number
IR.TUMS.CHMC.REC.1401.106

Health conditions studied

1

Description of health condition studied
Respiratory failure
ICD-10 code
J96
ICD-10 code description
Respiratory failure, not elsewhere classified

2

Description of health condition studied
Upper respiratory tract obstruction
ICD-10 code
J39
ICD-10 code description
Other diseases of upper respiratory tract

3

Description of health condition studied
Prolong intubation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Short-term complications after tracheostomy (such as bleeding, expansion of air in the interstitium, obstruction of the tracheostomy tube, accidental decannulation)
Timepoint

The first week after tracheostomy
Method of measurement
Clinical visit

2

Description
Long-term complications after tracheostomy (such as wound complications around the tracheostomy site, granulation tissue around the stoma)
Timepoint
From one week after tracheostomy for at least 3 months
Method of measurement
Clinical visit

3

Description
Length of stay in ICU
Timepoint
Length of stay in ICU after tracheostomy
Method of measurement
Clinical visit

4

Description
Duration of hospitalization
Timepoint
Hospitalization period after tracheostomy
Method of measurement
Clinical visit

5

Description
Duration of sedation after surgery
Timepoint
After tracheostomy until the cessation of sedative drugs
Method of measurement
Clinical visit

6

Description
Discharge status
Timepoint
Patient follow-up up to 3 months after tracheostomy
Method of measurement
Clinical visit

7

Description
Time of decannulation
Timepoint
Patient follow-up up to 3 months after tracheostomy
Method of measurement
Clinical visit

Secondary outcomes

empty

Intervention groups

1

Description
Control group: The first change of the tracheostomy tube on the 7th day
Category
Other

2

Description
Intervention group: First change of tracheostomy tube on the 3rd day
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Children's Medical Center
Full name of responsible person
Fatemeh Mir Ashrafi M.D
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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The headquarters of Tehran University of Medical Sciences, 6th floor, corner of Qods st, Keshavarz Blvd
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Research and Technology Vice-Chancellor
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
Tehran University of Medical Sciences
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Zeynab Agahi Kesheh
Position
Resident
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Person responsible for updating data

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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
Yes - There is 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

Checklist containing demographic information, indication of tracheostomy, short and long-term complications, duration of patient's stay in ICU and hospital, duration of receiving sedative drugs, and discharge status.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Access to the data in order to know the details of the data related to each participant Not to be used in a separate study without the knowledge and coordination of the researcher Non-disclosure of data without the researcher's knowledge and coordination Conducting independent statistical analyzes on data in separate studies without the knowledge and coordination of the researcher

From where data/document is obtainable

Zeynab Agahi Kesheh M.D z_a_k_1991@yahoo.com 00989307805236

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

Data request in email format Sending study records A detailed explanation of the reason for the need to access the data A detailed explanation of how the data will be used Check the description by the relevant team Deciding on the possibility of sharing data If the study team agrees, send the data to the requester

Comments