Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 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)

Phone

+98 21 6119 2393

Email address

z_a_k_1991@yahoo.com

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

Street address

Children's Medical Center, No62, Dr Gharib St, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733151

Phone

+98 21 6147 2051

Fax

+98 21 6693 0024

Email

cmcpr@tums.ac.ir

Web page address

https://enchmc.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

The headquarters of Tehran University of Medical Sciences, 6th floor, corner of Qods st, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Phone
+98 21 8163 3685

Fax
+98 21 8163 3125

Email
vcr@sina.tums.ac.ir

Web page address
https://vcr.tums.ac.ir

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

Full name of responsible person
Zeynab Agahi Kesheh

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Ear, Nose, and Throat

Street address
4th Floor, Vali Asr Building, Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
۱۴۱۹۷۳۳۱۴۱

Phone
+98 21 6119 2393

Email
z_a_k_1991@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Fatemeh Mir Ashrafi M.D

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Ear, Nose, and Throat

Street address
4th Floor, Vali Asr Building, Imam Khomeini Hospital Complex, Tohid Squre

City
Tehran

Province
Tehran

Postal code
۱۴۱۹۷۳۳۱۴۱

Phone
+98 21 6119 2393

Email
F-mirashrafi@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Zeynab Agahi Keshe

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Ear, Nose, and Throat

Street address
4th Floor, Vali Asr Building, Imam Khomeini Hospital Complex, Tohid Squre

City
Tehran

Province
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Postal code
۱۴۱۹۷۳۳۱۴۱

Phone
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Email
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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