

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of early and late tracheostomy in the outcome of multitrauma intubated patients

Protocol summary

Study aim

Comparison of early and late tracheostomy in the outcome of multitrauma intubated patients

Design

This study is a randomized clinical trial (blocks of four), double-blind (participants and results analyzer), with parallel groups, without control group and phase 1-2 and with the participation of 80 trauma patients candidates for tracheostomy referred to Imam Reza Hospital.

Settings and conduct

In this double-blind clinical trial study (participants and results analyzer), patients will undergo surgery by one of the two methods of early and late tracheostomy after random allocation in the two mentioned groups. Early tracheostomy is defined as performing tracheostomy during the first seven days of mechanical ventilation and late tracheostomy is also defined as performing tracheostomy after seven days of intubation.

Participants/Inclusion and exclusion criteria

The inclusion criteria: trauma patients, the duration of ventilation is more than 48 hours and the duration of mechanical ventilation is estimated by the doctor to be at least more than 21 days, and the exclusion criteria: severe injuries to the chest or neck, burns in the neck and patients will be drowned.

Intervention groups

Patients will undergo surgery by one of the two methods of early and late tracheostomy after random allocation in the two mentioned groups. Early tracheostomy is defined as performing tracheostomy during the first seven days of mechanical ventilation and late tracheostomy is also defined as performing tracheostomy after seven days of intubation.

Main outcome variables

Successful weaning from mechanical ventilation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N38**
Registration date: **2023-11-25, 1402/09/04**
Registration timing: **prospective**

Last update: **2023-11-25, 1402/09/04**

Update count: **0**

Registration date

2023-11-25, 1402/09/04

Registrant information

Name

Mehdi Khanbabayi Gol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 7054

Email address

khanbabayimehdi69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-19, 1402/09/28

Expected recruitment end date

2024-03-18, 1402/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of early and late tracheostomy in the outcome of multitrauma intubated patients

Public title

Comparison of early and late tracheostomy in the outcome of intubated patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Trauma patients Duration of ventilation more than 48 hours Estimated duration of mechanical ventilation by the doctor at least more than 21 days

Exclusion criteria:

Severe injuries to the chest or neck Burns in the neck Drowning patients

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, with a sample size of 80, we use the patients using the block permutation randomization method, which is used in this method to balance the number of allocated samples, and with 4 people in each block. We assemble the possible blocks as follows. block 1: BBAA, block 2: AABB, block 3: ABAB, block 4: BABA, block 5: ABBA, and block 6: BAAB, we need 20 blocks for 80 people. It is random in the block method. We choose numbers from one to six. For example, if number 6 is chosen as the first block and number 2 as the second block, the people who enter the study will be given BAABAABB in order from left to right. and finally they were divided into two intervention groups (group A) and control group (group B).

Blinding (investigator's opinion)

Double blinded

Blinding description

The thesis results analyst who will analyze the expected result and also the participants will be unaware of the type of procedure performed and will be blind during the study; Therefore, this study will be conducted in a double-blind manner.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Approval date

2023-04-16, 1402/01/27

Ethics committee reference number

IR.TBZMED.REC.1402.035

Health conditions studied

1

Description of health condition studied

Successful weaning from mechanical ventilation

ICD-10 code

Z93.0

ICD-10 code description

Tracheostomy status

Primary outcomes

1

Description

Weaning from mechanical ventilation

Timepoint

Once during the study

Method of measurement

Clinical observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients will undergo surgery by early tracheostomy after random allocation in the mentioned group. Early tracheostomy is defined as performing tracheostomy during the first seven days of mechanical ventilation. The success rate of weaning from mechanical ventilation for these patients will be recorded.

Category

Prevention

2

Description

Control group: Patients will be subjected to late tracheostomy surgery after random allocation in the mentioned group. Late tracheostomy is defined as performing tracheostomy after the first seven days of mechanical ventilation. The success rate of weaning from mechanical ventilation for these patients will be recorded.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital

Full name of responsible person

Mehdi Khanbabayi Gol

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

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

Tabriz University of Medical Sciences

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

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

Nursery

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

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