# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 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

**Street address**
Shahid Madani Hospital, Azadi Ave

**City**
Tabriz

**Province**
East Azarbaijan

**Postal code**
5981764863

**Phone**
+98 41 3535 3696

**Email**
mkhanbabayi@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Tabriz University of Medical Sciences

**Full name of responsible person**
Abolghasem Jouyban

**Street address**
Imam Reza Hospital, Azadi Ave

**City**
Tabriz

**Province**
East Azarbaijan

**Postal code**
5165665631

**Phone**
+98 41 3335 7310

**Email**
Ajouyban@hotmail.com

**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

**Street address**
Imam Reza Hospital, Azadi Ave

**City**
Tabriz

**Province**
East Azarbaijan

**Postal code**
5981764863

**Phone**
+98 41 3334 7054

**Fax**

**Email**
Khanbabayimehdi69@gmail.com

## Person responsible for scientific 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

**Street address**
Imam Reza Hospital, Azadi Ave

**City**
Tabriz

**Province**
East Azarbaijan

**Postal code**
5981764863

**Phone**
+98 41 3334 7054
**Fax**
**Email**
Khanbabayimehdi69@gmail.com

## Person responsible for updating data

**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
**Street address**
Imam Reza Hospital, Azadi Ave
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5981764863
**Phone**
+98 41 3334 7054
**Fax**
**Email**
Khanbabayimehdi69@gmail.com

## 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