

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### " The effect of systemic corticosteroids in the management of patients with post intubation tracheal stenosis"

#### Protocol summary

##### Summary

Aim: The effect of systemic corticosteroids in the management of patients with post intubation tracheal stenosis. Inclusion criteria: All patients with post intubation tracheal stenosis who are not ideal candidate for airway surgery at the time of first presentation. Exclusion criteria: patients presented with tracheostomy or t-tube; patients presented 6 months after the intubation time; patients younger than 15 years old. Population: The patients with post intubation tracheal stenosis Sample size: 120 patients Intervention: drug/placebo, both the participants and the investigators are blinded regarding the intervention Time of intervention: Intervention is performed after the first bronchoscopy for 6 months. Outcome: the number of patients who should finally undergo airway resection, the length of resected tracheal segment, the number of bronchoscopic procedures, the time intervals between bronchoscopic procedures before an airway resection

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014103019760N1**  
Registration date: **2014-12-22, 1393/10/01**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-12-22, 1393/10/01

##### Registrant information

##### Name

Mohammad Behgam Shadmehr

##### Name of organization / entity

Tracheal Diseases Research Center, NRITLD, Shahid

Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

National Research Institute of Tuberculosis and Lung Diseases

##### Expected recruitment start date

2009-01-20, 1387/11/01

##### Expected recruitment end date

2012-11-21, 1391/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

" The effect of systemic corticosteroids in the management of patients with post intubation tracheal stenosis"

##### Public title

Do systemic corticosteroids have any role in the management of Post-Intubation Tracheal Stenosis? A randomized clinical trial

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: All patients with post intubation tracheal stenosis who are not ideal candidate for airway surgery at the time of first presentation. Exclusion criteria: patients presented with tracheostomy or t-tube; patients presented 6 months after the intubation time;

patients younger than 15 years old.

#### Age

From **15 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **120**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Shahid Beheshti university of medical sciences, National Research institute of Tu

###### Street address

Masih Daneshvari hospital, Daar Abad, Niavaran, Tehran, Iran

###### City

Tehran

###### Postal code

##### Approval date

2008-12-18, 1387/09/28

##### Ethics committee reference number

C-87-778

### Health conditions studied

#### 1

##### Description of health condition studied

Tracheal Stenosis

##### ICD-10 code

J39.8

##### ICD-10 code description

Other specified diseases of upper respiratory tract

### Primary outcomes

#### 1

##### Description

the number of patients who undergo airway resection;

##### Timepoint

6 months following end of intervention

##### Method of measurement

the number of patients who undergo airway surgery

#### 2

##### Description

the length of resected tracheal segment

##### Timepoint

whenever the resection and anastomosis of the trachea is performed.

##### Method of measurement

rigid bronchoscopy, pathology report

### Secondary outcomes

#### 1

##### Description

the number of bronchoscopies

##### Timepoint

before an airway resection

##### Method of measurement

counting the number of bronchoscopies before surgery

#### 2

##### Description

the time intervals between bronchoscopic procedures

##### Timepoint

before an airway resection

##### Method of measurement

days interval between bronchoscopic procedures

### Intervention groups

#### 1

##### Description

Intervention group: drug: capsule containing 15 mg of prednisolon ; dose: one capsule/day; time of consumption: 6 months

##### Category

Treatment - Drugs

#### 2

##### Description

Control group: placebo: capsule with no medicine; dose: one capsule/day; time of consumption: 6 months

##### Category

Placebo

### Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

National research Institute of Tuberculosis and Lung diseases, Masih Daneshvai Hospital

**Full name of responsible person**

Dr. Roya Farzanegan

**Street address**

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for National research institute of tuberculosis and lung diseases, Dr Massih Daneshva

**Full name of responsible person**

Dr. Hamidreza Jamaati, associate Professor of critical care

**Street address**

Dr Massih Daneshvari hospital, Daar Abad, Niavaran, Tehran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for National research institute of tuberculosis and lung diseases, Dr Massih Daneshva

**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**

Tracheal Diseases Research Center, NRITLD, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammad Behgam Shadmehr

**Position**

Professor of surgery

**Other areas of specialty/work**

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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*