

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

+98 21 2712 2016

Email address

mbshadmehr@sbmu.ac.ir

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

Street address

NRITLD, Masih Daneshvari Hospital, Daar Abad Niavaran, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 2610 5387

Fax

Email

mbshadmehr@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tracheal diseases research center, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Behgam Shadmehr

Position

Professor of Surgery

Other areas of specialty/work

Street address

NRITLD, Masih Daneshvari Hospital, Daar Abad, Niavarn, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 2610 5387

Fax

Email

mbshadmehr@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

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

Full name of responsible person

Roya Farzanegan

Position

MD, PhD by research student

Other areas of specialty/work

Street address

Masih Daneshvari hospital, Daar Abad Niavaran, Tehran

City

Tehran

Postal code

19569-44413

Phone

+98 21 2610 5387

Fax

Email

royafarzanegan@yahoo.com

Web page address

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