

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Investigating the effect of prednisolone in the bronchoscopic procedure in the treatment of patients with tracheal stenosis

Protocol summary

tracheal stenosis

Study aim

Determining the effect of prednisolone in bronchoscopic procedure in the treatment of patients with tracheal stenosis referred to Shahid Beheshti Hospital in 1401

Design

A clinical trial with a control group, with parallel groups, 1 blind, randomized, phase 0 on 40 patients. It will be generated from R software for randomization

Settings and conduct

Two control groups (n=20), patients who undergo bronchoscopy, undergo repeated bronchoscopy 3 weeks later (21 days) without receiving any medication (placebo), and the second group of patients after the first stage bronchoscopy, for 3 weeks. They receive 0.5 mg/kg prednisolone daily and after 21 days, they undergo bronchoscopy again.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Patients suffering from tracheal stenosis. 2) Patients who have a stenosis equal to less than 1.5 cm. 3) Patients who are candidates for rigid bronchoscopy. Exit criteria: 1) Patients who are candidates for bronchoscopy due to other diseases (except for tracheal stenosis). 2) Patients whose stenosis length is more than 1.5 cm. 3) Patients suffering from underlying diseases for whom corticosteroid administration is contraindicated.

Intervention groups

In this study, the statistical sample is divided into two groups (n=20), so that in the control group, patients who undergo bronchoscopy, 3 weeks later (21 days) without receiving any medicine (receive placebo), undergo bronchoscopy again. And in the second group of patients, after the first stage bronchoscopy, they receive 0.5 mg/kg prednisolone (26) daily for 3 weeks and after 21 days, they undergo bronchoscopy again.

Main outcome variables

Treating patients with tracheal stenosis and preventing or minimizing complications caused by bronchoscopy and improving the course of treatment of patients with

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230410057872N1**

Registration date: **2023-04-26, 1402/02/06**

Registration timing: **prospective**

Last update: **2023-04-26, 1402/02/06**

Update count: **0**

Registration date

2023-04-26, 1402/02/06

Registrant information

Name

HOSEIN Fallah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3771 9337

Email address

dr_fallah69@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of prednisolone in the bronchoscopic procedure in the treatment of patients with tracheal stenosis

Public title

Investigating the effect of prednisolone in the bronchoscopic procedure in the treatment of patients with tracheal stenosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1) Patients suffering from tracheal stenosis.2) Patients who have a stenosis equal to less than 1.5 cm.3) Patients who are candidates for rigid bronchoscopy

Exclusion criteria:

1) Patients who are candidates for bronchoscopy due to other diseases (except for tracheal stenosis).2) Patients whose stenosis length is more than 1.5 cm.3) Patients suffering from underlying diseases for whom corticosteroid administration is contraindicated.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

0

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization method will be used. First, we identify the patients who meet the conditions for entering the study. Then, using the randomization list that will be generated using R software, people will be randomly assigned to each of the treatment groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the statistical sample is divided into two groups (n=20), so that in the control group, patients who undergo bronchoscopy, 3 weeks later (21 days) without receiving any medicine (receive placebo), undergo bronchoscopy again. And in the second group of patients, after the first stage bronchoscopy, they receive 0.5 mg/kg prednisolone daily for 3 weeks and after 21 days, they undergo bronchoscopy again.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qom University of Medical Sciences

Street address

Qom University of Medical Sciences

City

Qom

Province

Ghoum

Postal code

3713649373

Approval date

2023-03-13, 1401/12/22

Ethics committee reference number

IR.MUQ.REC.1401.247

Health conditions studied

1

Description of health condition studied

Tracheal stenosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Treatment of tracheal stenosis

Timepoint

3 weeks later (21 days)

Method of measurement

Bronchoscopy

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients who receive 0.5 mg/kg of prednisolone daily for 3 weeks after first-stage bronchoscopy.

Category

Treatment - Drugs

2

Description

Control group: Patients who undergo bronchoscopy will undergo another bronchoscopy 3 weeks later (21 days) without receiving any medication (placebo).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Qom

Full name of responsible person

Hossein Falah

Street address

Qom University of Medical Sciences

City

Qom

Province

Ghous

Postal code

3713649373

Phone

+98 25 3107 1100

Email

dr_fallah69@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Dr. Rahim Alei

Street address

Qom University of Medical Sciences

City

Qom

Province

Ghous

Postal code

3713649373

Phone

+98 25 3107 1100

Email

dr_fallah69@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ghous 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

Ghous University of Medical Sciences

Full name of responsible person

Hossein Falah

Position

Surgical resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

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Person responsible for updating data

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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

All the data will be published in the article and thesis after removing the names of the patients

When the data will become available and for how long

3 months after printing the results

To whom data/document is available

محققین شاغل در موسسات دانشگاهی و علمی

Under which criteria data/document could be used

For scientific research

From where data/document is obtainable

Hossein Falah dr_fallah69@yahoo.com

What processes are involved for a request to access data/document

Submit an academic application and a description of your study and the need for data for this study

Comments