Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

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 tracheal stenosis

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
HOSEEIN 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
Ghoum
Postal code
3713649373
Phone
+98 25 3107 1100
Email
dr_fallah69@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Dr. Rahim Alei
Street address
Qom University of Medical Sciences
City
Qom
Province
Ghoum
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
Ghoum 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
Ghoum 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
Qom University of Medical Sciences
City
Qom
Province
Ghoum
Postal code
3713649373
Phone
+98 25 3107 1100
Email
dr_fallah69@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ghoum 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
Qom University of Medical Sciences
City
Qom
Province
Ghoum
Postal code
3713649373
Phone
+98 25 3107 1100
Email
dr_fallah69@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Ghoum University of Medical Sciences

Full name of responsible person
Hossein Falah

Position
General Surgery

Latest degree
Medical doctor

Other areas of specialty/work
General Surgery

Street address
Qom University of Medical Sciences

City
Qom

Province
Ghoum

Postal code
3713649373

Phone
+98 25 3107 1100

Email
dr_fallah69@yahoo.com

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