Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Sep 2026

Comparison of the Effectiveness of two treatment protocols of balloon dilatation and administration of methotrexate as an auxiliary treatment for patients with tracheal stenosis due to intubation

Protocol summary

Study aim

Comparison of two treatment protocols of balloon dilatation and administration of methotrexate as an auxiliary treatment for patients with tracheal stenosis due to intubation

Design

Two arm parallel group randomized trial with blinded postoperative care and outcome assessment

Settings and conduct

This clinical trial study will be performed on patients referred to bronchoscopy ward of Masih Daneshvari Hospital. Patients who have been diagnosed based on the results of their clinical examinations, spirometry and diagnostic bronchoscopy, will be included in the study and will be randomly divided into two groups. Patients in group 1 will undergo balloon dilatation. In the second group, methotrexate will be used every two weeks. Patients will be followed for the first month every week and then at 3 and 6 months.

Participants/Inclusion and exclusion criteria

The patients referred to the bronchoscopy ward of Masih Daneshvari Hospital who were diagnosed with the results of medical and paraclinical examinations will be included in the study and will be randomly divided into two groups. Obviously, only patients with tracheal stenosis after intubation will be included in the study and tracheal stenosis due to other reasons including congenital and primary and metastatic malignancies as well as vasculitis such as Wegener's disease will be excluded.

Intervention groups

Patients in group 1 undergo balloon dilatation and the second group receive methotrexate at a dose of 15 mg twice weekly for stenosis.

Main outcome variables

the length of stenosed section severity of stenosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170531034256N3**
Registration date: **2020-02-04, 1398/11/15**
Registration timing: **retrospective**

Last update: **2020-02-04, 1398/11/15**
Update count: **0**

Registration date

2020-02-04, 1398/11/15

Registrant information

Name

Atefeh Abedini

Name of organization / entity

Chronic Respiratory Diseases Research Center, National Research Institute of Tuberculosis and Lung D

Country

Iran (Islamic Republic of)

Phone

+98 21 2712 2031

Email address

dr.abedini110@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

2019-03-21, 1398/01/01

Actual recruitment end date

2019-06-22, 1398/04/01

Trial completion date

2019-12-22, 1398/10/01

Scientific title

Comparison of the Effectiveness of two treatment protocols of balloon dilatation and administration of methotrexate as an auxiliary treatment for patients with tracheal stenosis due to intubation

Public title

Effect of two treatment protocols of balloon dilatation and administration of methotrexate in tracheal stenosis due to intubation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with a diagnosis according to the results of medical and paraclinical examinations Patients with tracheal stenosis caused by intubation

Exclusion criteria:

congenital tracheal stenosis as well as tracheal stenosis are excluded. Patients with tracheal stenosis due to primary or metastatic malignancies Patients with tracheal stenosis due to vasculitis such as Wegener's disease

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **10**

Actual sample size reached: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned to groups 1 or 2 , using a single computer-generated (nQuery Advisor) random number sequence by a physician.

Blinding (investigator's opinion)

Double blinded

Blinding description

A statistician will classify the patients using a single computer-generated (nQuery Advisor) random number sequence in either group one (control group) or group 2 (intervention group). This person is unaware of the type of treatment which they will receive in each group. Patients will be informed about two potential types of treatment but they won't know they will receive which of those.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of National Research Institute of Tuberculosis and Lung Diseases (NRITLD), Shahid B

Street address

Masih Daneshvari Hospital, DAR ABAD

City

Tehran

Province

Tehran

Postal code

19569-44413

Approval date

2020-01-21, 1398/11/01

Ethics committee reference number

IR.SBMU.NRITLD.REC.1398.084

Health conditions studied

1

Description of health condition studied

patients with tracheal stenosis due to intubation

ICD-10 code

J39.8

ICD-10 code description

Other specified diseases of upper respiratory tract

Primary outcomes

1

Description

Need for surgical treatment at follow-up

Timepoint

Every week in the first month- month 3- month 6

Method of measurement

Physician diagnosis

Secondary outcomes

1

Description

side effects

Timepoint

every week in the first month- month 3- month 6

Method of measurement

Interview - Examination

Intervention groups

1

Description
Intervention group: Methotrexate will be used every two weeks and patients will be followed every week in the first month and then at month 3 and 6.

Category
Treatment - Drugs

2

Description
Control group: They will undergo local anesthesia and sedation and then bronchoscopy immediately before performing the dilatation balloon, with the aim of determining the location of the stenosis and designing the protocol for the patients. After the last balloon dilation, patients will be monitored for 2-4 hours.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Bronchoscopy Department of Masih Daneshvari Hospital

Full name of responsible person
Atefeh Abedini

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Masih Daneshvari Hospital, Dar Abad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

Street address
Masih Daneshvari hospital, Dar Abad

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zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Negar Bandegani

Position
General Practitioner-Researcher

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Person responsible for scientific inquiries

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Shahid Beheshti University of Medical Sciences

Full name of responsible person
Arda Kiani

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

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Person responsible for updating data

Contact
Name of organization / entity
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Atefeh Abedini
Position
assistance professor
Latest degree
Subspecialist
Other areas of specialty/work
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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