

# Clearing blocked airways: A Dutch study on a new bronchoscopy treatment

<b>Submission date</b> 31/01/2025	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/02/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/02/2025	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Central airway obstruction occurs in the trachea and main bronchi and can occur due to malignant and non-malignant causes. It can lead to severe respiratory symptoms. Treatment is often physician-dependent due to a lack of standardized guidelines. This study aims to systematically document the clinical, anatomical, and procedural characteristics of central airway obstruction patients undergoing therapeutic bronchoscopy in the Netherlands. Secondary objectives include evaluating procedure-related complications and identifying prognostic factors.

### Who can participate?

Patients diagnosed with central airway obstruction who require therapeutic bronchoscopy, as determined by their treating physician, will be eligible for inclusion. Both flexible and rigid bronchoscopies will be considered.

### What does the study involve?

Participants will undergo bronchoscopy, with data collection including patient demographics, obstruction characteristics, treatment details and outcomes. The study will follow standardized definitions and protocols to ensure consistency across participating centers.

### What are the possible benefits and risks of participating?

This is a registry study that will document the possible benefits and risks based on real-life data.

### Where is the study run from?

The study will be conducted across eight Dutch interventional pulmonology centers, including Amsterdam UMC, Antoni van Leeuwenhoek Hospital, Radboud UMC, Amphia Hospital, UMC Groningen, Erasmus MC, Maastricht UMC and Leiden UMC.

### When is the study starting and how long is it expected to run for?

January 2025 to February 2026. The study will start recruiting on February 1st, 2025, and run for 12 months, followed by three months for data analysis and publication.

Who is funding the study?

The study is institutionally approved and governed by The Netherlands Cancer Institute - Antoni van Leeuwenhoekziekenhuis (NKI-AVL)

Who is the main contact?

Dr. I. Smesseim, i.smesseim@nki.nl

## Contact information

### Type(s)

Principal Investigator

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

Nil known

## Study information

### Scientific Title

Therapeutic bronchoscopy for central airway obstructions: a Dutch multicenter prospective registry study (NVALT36)

### Acronym

NVALT36

### Study objectives

To describe the clinical, anatomical, and procedural characteristics of CAO patients treated with therapeutic bronchoscopy

### Ethics approval required

Ethics approval required

### Ethics approval(s)

Approved 27/01/2025, Institutional Review Board (IRB) of The Netherlands Cancer Institute (Plesmanlaan 121, Amsterdam, 1066 CX, Netherlands; +31 (0)20 51291; IRB@nki.nl), ref: IRBd23-334

### Study design

Multicenter observational prospective registry study

### Primary study design

Observational

### Secondary study design

Cohort study

### Study setting(s)

Hospital, Medical and other records

### Study type(s)

Diagnostic

### Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

### Health condition(s) or problem(s) studied

Central airway obstruction (defined as an obstruction in the trachea, right or left main bronchus, or bronchus intermedius on imaging or by direct visualization during bronchoscopy) necessitating therapeutic bronchoscopy

### Interventions

When the patient gives consent to participate in the study, only information (patient characteristics, demographics, airway obstruction characteristics and symptoms, procedure,

characteristics of airway obstruction and symptoms) will be recorded. The patient will not receive any additional treatment and will not notice anything further from participating in the study.

#### **Data analyses**

Differences between groups will be estimated using chi-square, Fisher's exact, and independent two-sample t-tests. The chi-square test and Fisher's test will be used to compare the incidence of complications between two or more groups. A multivariate logistic regression model will be performed using logistic regression to identify prognostic factors associated with procedure-related complications.

#### **Intervention Type**

Other

#### **Primary outcome measure**

Clinical, anatomical, and procedural characteristics at baseline of patients with central airway obstruction treated with therapeutic bronchoscopy measured using data collected during the procedure at one timepoint

#### **Secondary outcome measures**

The following secondary outcome measures are assessed using data collected during the procedure at one timepoint:

1. Procedure-associated complications
2. Prognostic factors associated with the procedure

#### **Overall study start date**

01/01/2025

#### **Completion date**

01/02/2026

## **Eligibility**

#### **Key inclusion criteria**

1. Central airway obstruction (defined as obstruction in the trachea, right or left main bronchus, or bronchus intermedius on imaging or by direct visualization during bronchoscopy) as determined by the treating physician necessitating therapeutic bronchoscopy
2. Adults ( $\geq 16$  years)

#### **Participant type(s)**

Patient

#### **Age group**

Mixed

#### **Lower age limit**

16 Years

#### **Sex**

Both

**Target number of participants**

500

**Key exclusion criteria**

<16 years

**Date of first enrolment**

01/02/2025

**Date of final enrolment**

01/02/2026

**Locations****Countries of recruitment**

Netherlands

**Study participating centre**

**Antoni van Leeuwenhoek hospital / NKI**

Plesmanlaan 121

Amsterdam

Netherlands

1066 CX

**Study participating centre**

**University Medical Center Groningen**

Hanzeplein 1

Groningen

Netherlands

9713 GZ

**Study participating centre**

**Radboud University Medical Center**

Geert Grooteplein Zuid 10

Nijmegen

Netherlands

6525 GA

**Study participating centre**

**Amsterdam University Medical Centers**

De Boelelaan 1117

Amsterdam

Netherlands  
1081 HV

**Study participating centre**

**Amphia Hospital**

Molengracht 21  
Breda  
Netherlands  
4818 CK

**Study participating centre**

**Leiden University Medical Center**

Albinusdreef 2  
Leiden  
Netherlands  
2333 ZA

**Study participating centre**

**Maastricht University Medical Center**

P. Debyelaan 25  
Maastricht  
Netherlands  
6229 HX

**Study participating centre**

**Erasmus Medical Center**

Dr. Molewaterplein 40  
Rotterdam  
Netherlands  
3015 GD

## **Sponsor information**

**Organisation**

The Netherlands Cancer Institute

**Sponsor details**

Plesmanlaan 121  
Amsterdam

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+31 20 512 9111  
not@available.com

**Sponsor type**

Hospital/treatment centre

**Website**

<https://www.nki.nl>

**ROR**

<https://ror.org/03xqtf034>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Netherlands Cancer Institute

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a peer-reviewed journal

**Intention to publish date**

01/05/2026

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. I. Smesseim, [i.smesseim@nki.nl](mailto:i.smesseim@nki.nl).

**Data management plan**

- What data are you going to collect?

The data we want to collect are as follows: Age, gender, comorbidities, smoking history, pack years, ECOG performance status, cause of interventional pulmonology procedure, cause of central airway obstruction, type of airway obstruction, respiratory symptoms, MRX dyspnea scale, emergency of procedure, type of anesthesia, type of ventilation during the procedure, type of bronchoscope, Meyer Cottons stenosis grade, debulking technique, complications during the procedure, complications within 24hrs, stent placement, stent material, stent shape, stent characteristics, procedure time.

- Where and how are you going to store your data?

All participating center will register the information in a national database (Castor)

- Who will have access to your data? When? How will you manage that access?

The researcher from AVL and the Principal Investigator (PI) will have access to the data.

- Which data will be archived at the end of the project? Where, and for how long?

The previously mentioned data that we want to collect (see the first question) will be archived for ten years after the publication of the data.

- Will the archived data become available to others? When? Under which license?

The archived data will not be available to others. If there is a new research question that requires (part of) the database to be used, we expect a physician-researcher from AVL to submit a new IRB application clearly describing the data they wish to use. This must be evaluated by the IRB.

- Who is the owner of your data? Who is responsible for managing your data?

The researcher (NKI) and principal investigator of the study (NKI)

- Which resources are needed for this plan?

Castor Database

## IPD sharing plan summary

Stored in non-publicly available repository, Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other files</a>			13/02/2025	No	No