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

Submission date
31/01/2025

Recruitment status
Recruiting

Registration date
28/02/2025

Overall study status
Ongoing

Last Edited
13/02/2025

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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
Mr Jacobus A Burgers

Contact details
Netherlands Cancer Institute
Plesmanlaan 121
Amsterdam
Netherlands
1066 CX
+31 20 512 9111
s.burgers@nki.nl

Type(s)
Public, Scientific

Contact name
Ms Illaa Smesseim

Contact details
Netheralnds Cancer Institute
Plesmanlaan 121
Amsterdam
Netherlands
1066 CX
+31 20 512 9111
i.smesseim@nki.nl

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Diagnostic

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(s)
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

Key secondary outcome(s))
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

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 (≥16 years)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Sex
All

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

ROR
https://ror.org/03xqtf034

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Netherlands Cancer Institute

Results and Publications

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.

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?
Other files			13/02/2025	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes