Bronchial thermoplasty (BT) for severe asthma in the biologic era: a randomized controlled trial (BOOSTER trial)

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To investigate the impact of BT as compared to standard of care in severe asthma patients that remain uncontrolled despite standard treatment including adequate doses of inhaled preventer therapies with or without biologics on:(1) rate of...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON56716

Source
ToetsingOnline

Brief title
BOOSTER trial

Condition

- Bronchial disorders (excl neoplasms)

Synonym
asthma, asthmatic bronchitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW - ZIN

Intervention

Keyword: Asthma, Bronchial thermoplasty

Outcome measures

Primary outcome

Between group difference in severe exacerbation rate after 12 months of follow-up.

Secondary outcome

Between and before and after group differences after follow-up of (6 and) 12 months in:

- AQLQ

- ACQ

- Exacerbation rate

- Time to first severe exacerbation

- % subjects with severe exacerbation

- Emergency department visits (rate and % subjects)

- Hospitalizations (rate and % subjects)

- % subjects with OCS reduction 50% or more

- % subjects with biologics stop

- Pulmonary function testing (FEV1, FEV1 reversibility, PC20 if available)

- Asthma control biomarkers (FENO, blood eosinophils)

- Adverse events from BT

- EQ-5D-5

- Costs (including Productivity Costs Questionnaire (PCQ)

- SAQ (optional)

Study description

Background summary

For patients with severe asthma that remain uncontrolled with exacerbations despite biologics or patients who are not eligible for biologics, there is no reimbursed treatment other than pulmonary rehabilitation in the Netherlands. Pulmonary rehabilitation is known to have a limited effect for a limited amount of time. Bronchial thermoplasty or bronchial ablation (BT) is a non-pharmacological treatment for asthma aiming to restore abnormal airway function by using an endobronchial approach. Previous RCT*s reported efficacy on exacerbations and asthma related quality of life (AQLQ), but were performed before large availability of biologic treatments. Although a single BT treatment is not without costs, these costs seem to outweigh the costs that can be saved by the long-term (>5 years) lowering effect of BT on the frequency of exacerbations and hospitalizations and omitting long term use of trials and switches of biologics. Therefore, we hypothesize that BT, in the era of biologics, is superior (in terms of exacerbations and quality of life) over standard care and cost-effective in patients whose asthma remains uncontrolled despite optimal anti-inflammatory treatments including biologics, and we propose to test this hypothesis in a RCT.

Study objective

To investigate the impact of BT as compared to standard of care in severe asthma patients that remain uncontrolled despite standard treatment including adequate doses of inhaled preventer therapies with or without biologics on:
(1) rate of exacerbations
(2) asthma related quality of life (AQLQ)
(3) 1-year and 5-year cost-effectiveness and cost utility

Study design

Investigator-initiated randomized, multicenter, parallel-group interventional RCT of severe asthma patients undergoing either BT (active arm) or standard care (control arm).

Intervention

BT (active arm) versus standard care (control arm).

Study burden and risks

BT efficacy has been demonstrated in previous studies, although with varying levels of magnitude and across variable populations at the expense of a relatively small number of expected and manageable adverse events limited to the initial BT-treatment period. Therefore, we propose that in selected patients with severe uncontrolled asthma with reduced quality of life and frequent exacerbations despite optimal (anti-inflammatory) treatment, BT is a treatment option with high potential in terms of (long term) clinical efficacy and cost-effectiveness. The patient benefit of study participation is that he/she is offered a severe asthma treatment that is proven effective and safe with potential lifelong benefit but unfortunately not regularly available yet. Patients will be randomized to an active group who receives the BT treatment and a standard of care group. The total duration of the study, including follow-up is approximately 15 months. In the active BT treatment group, patients undergo a total of three bronchoscopies with 3 weeks in between. First, the right lower lobe is treated, followed by the left lower lobe and during the last session both upper lobes are treated. The bronchoscopies will be performed under tailored sedation ranging from conscious sedation (eg midazolam or propofol) to deep sedation/general anaesthesia to minimize patient discomfort. Previous experiences in bronchoscopies and BT treatment in severe asthma patients by our group and other have proven to be safe. Patients will be treated with prednisolone three days before the procedure, on the day itself and one day thereafter. During the *treatment period*, patients are offered one-night hospital stay directly after BT for clinical observation and exacerbations or transient increase in respiratory symptoms will be treated with steroids, if considered necessary by the attending pulmonologists. The *treatment period* ends six weeks after the final (third) BT-procedure is and the (post-treatment) *follow-up period* starts that will last 12 months. After this treatment period and during the *follow-up period*, study visits (either physical or by phone) at 3, 6, 9 and 12 months will be performed, and more often if deemed necessary due to disease activity or to monitor treatment changes. The following assessments will be completed: ACQ, AQLQ, EQ-5D-5, PCQ, SAQ, and monitoring of exacerbations/hospitalizations/ emergency department visitis, asthma medications, adverse events and lung function (spirometry) and biomarkers (FeNO and blood eosinophils) at 6 and 12 months. In line with GINA and NVALT guidelines on severe asthma, it is allowed to initiate additional treatments, such as initiation of new biologic treatment or referral for pulmonary rehabilitation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-adult (>18 years)
-severe uncontrolled asthma (defined as ACQ above 1.5) despite optimal medical therapy (GINA treatment step 5; alternative diseases excluded, therapy compliance and adequate inhalation technique confirmed)
-1 or more trials of treatment with a biologic or ineligible for biologic treatment
-2 or more severe asthma exacerbations in the previous year (defined as the need for a course of OCS or doubling dose of maintenance OCS for at least 3 consecutive days)
-FEV1 >= 50% predicted after 400µg inhaled salbutamol or equivalent

Exclusion criteria

-chronic OCS therapy at a dose >20 mg/day prednisone equivalent;
-anti-coagulation therapy that cannot be stopped temporarily
-comorbidities that are a contra-indication for BT (e.g. bronchiectasis, heart failure)

-pregnancy;
-body mass index >=35;
-current or ex-smokers with >20 pack years;
-DLCOc <70%
-Subject uses an internal or external pacemaker or cardiac defibrillator

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-05-2024
Enrollment:	90
Type:	Actual

Medical products/devices used

Generic name:	Bronchial thermoplasty of bronchial ablation
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	09-04-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL85642.018.23