Ten year follow-up of subjects from 3 randomized controlled Bronchial Thermoplasty (BT) studies.

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To confirm the long-term efficacy and safety of Bronchial Thermoplasty (BT) at 10 years follow-up or beyond in subjects previously enrolled in any of the following Boston Scientific-sponsored, controlled pre-approval studies: AIR, RISA and AIR2.No...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON46716

Source
ToetsingOnline

Brief title
BT 10+ Study

Condition

- Respiratory disorders NEC

Synonym
Astma

Research involving
Human

Sponsors and support

Primary sponsor: Boston Scientific Cooperation International
Source(s) of monetary or material Support: Boston Scientific Corporation

Intervention

Keyword: Alair treatment, Asthma, Bronchial Thermoplasty, Registry

Outcome measures

Primary outcome

SAFETY:

Absence of clinically significant post-treatment respiratory changes, following BT, defined as bronchiectasis or bronchial stenosis, as confirmed by Pulmonary HRCT scan at the BT 10+ study visit in those subjects who had a baseline HRCT scan in the AIR2 Study.

EFFECTIVENESS:

Durability of the treatment effect by comparing the proportion of subjects who experience severe asthma exacerbations during the first and fifth years after BT treatment with the proportion of subjects who experience severe asthma exacerbations during the 12 month period prior to the BT 10+ study visit.

Secondary outcome

The following additional endpoints will be evaluated for the 12 month period prior to the BT 10+ study visit and will be compared to the first and fifth years after BT treatment:

* Severe asthma exacerbation rates (exacerbations / subject / year)

* Emergency room visits for respiratory adverse events (rates of emergency room visits and proportion of subjects with emergency room visits for respiratory adverse events)

* Hospitalizations for respiratory adverse events (rates of hospitalizations

and proportion of subjects with hospitalizations for respiratory adverse events)

* Respiratory Serious Adverse Events (SAEs) (rates of respiratory SAEs, and

proportion of subjects with respiratory SAEs)

Study description

Background summary

The AlairTM Bronchial Thermoplasty System was developed as a novel system designed to deliver radiofrequency energy to the airways of asthmatic patients. Bronchial thermoplasty (BT) is a non-pharmacologic, bronchoscopic treatment for subjects 18 years and older with severe persistent asthma that is not well controlled with inhaled corticosteroids (ICS) and long-acting beta-agonists (LABA). During the BT procedure, radiofrequency energy is used to heat the airway walls in a controlled manner. The mechanism of action is, in part, a lasting reduction in Airway Smooth Musle mass due to the heat produced during the procedure. The reduction in Airway Smooth Musle was associated with the clinical improvement seen in patients undergoing BT. The BT 10+ study will be the first look at BT subjects beyond 5 years. The evaluation of baseline HRCT scans from the BT subjects from the AIR2 study and comparison to the 10 year follow-up HRCT scan will provide objective safety data to determine if significant post-treatment changes exist.

Study objective

To confirm the long-term efficacy and safety of Bronchial Thermoplasty (BT) at 10 years follow-up or beyond in subjects previously enrolled in any of the following Boston Scientific-sponsored, controlled pre-approval studies: AIR, RISA and AIR2.

No formal hypothesis will be tested. Data will be summarized descriptively with confidence intervals, as appropriate.

Study design

BT 10+ is an international multi-center, prospective follow-up study on subjects who were previously enrolled in any of the following studies: AIR, RISA and AIR2 trials. Subjects who received active BT treatment in any of the 3 trials will be eligible to participate upon achieving a minimum of at least 10 years* time from their last BT treatment*s 6-week follow-up.

Study burden and risks

The only new risks with the trial are those associated with HRCT scans and pulmonary function testing. It is an observational study, patients will visit the hospital once for ± 3 hours.

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

- Previously enrolled in AIR, RISA or AIR2
- Subjects who received active BT treatment and had last BT treatment at least 10 years follow-up

- Control/Sham subjects with at least 10 years of long-term follow-up

Exclusion criteria

Severe asthma exacerbation or chest infection in the past 4 weeks

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-04-2018
Enrollment:	7
Type:	Actual

Ethics review

Approved WMO

Date:	07-03-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT03243292
CCMO	NL63770.042.17