TASMA Extension Study: Long Term Efficacy and Safety of Bronchial Thermoplasty in Severe Asthma.

Published: 14-08-2015
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To evaluate long term safety, efficacy and airway remodelling effects of BT in patients with severe asthma.

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

Summary

ID

NL-OMON44139

Source
ToetsingOnline

Brief title
TASMA extension study

Condition

- Bronchial disorders (excl neoplasms)

Synonym
asthma, asthmatic bronchitis, reversible airway obstruction

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Airway smooth muscle, Asthma, Bronchial thermoplasty

Outcome measures

Primary outcome

Primary endpoint is the health care utilization (Emergency room visits, Hospitalizations, Severe exacerbations rate) measured yearly over 5 years and compared to the pre- and post BT-treatment.

Secondary outcome

Secondary endpoints are the following parameters measured over 5 years compared to the parameters measured pre- and post-BT treatment:

1). Clinical outcome parameters, including ACQ/ AQLQ scores, health care utilization (Emergency room visits, Hospitalizations, Severe exacerbations rate), medication, pulmonary function test (PC20 methacholine, pre- and post bronchodilator FEV1 and FEV1 % revesibility, FeNO, Airway-resistance (sRaw)/-conductance(sGaw)/-mechanics (forced oscillation technique (FOT))

Optional only for AMC / UMCG recruited patients:

2). ASM mass as determined by percentage/absolute ASM surface area and distance of reticular basement membrane (RBM) to ASM layer in endobronchial biopsies.

3). OCT determined changes in structural airway remodelling as measured by changes in lumen area (Ai) and airway wall thickness (Aaw).

Study description

Background summary

Bronchial Thermoplasty (BT) is a device-based severe asthma treatment based on local, radio-frequent energy delivery in the large airways that was developed to prevent excessive bronchoconstriction by reducing airway smooth muscle (ASM). The 5-year safety data of BT show a reduction in severe exacerbations, hospitalizations and emergency department visits and improvement in asthma symptoms in patients with severe asthma. Additional long term safety and efficacy data in severe asthma patients treated with BT are needed.

Study objective

To evaluate long term safety, efficacy and airway remodelling effects of BT in patients with severe asthma.

Study design

This will be an investigator-initiated multicenter, international prospective observational extension study of severe asthma patients who have previously been treated in the TASMA study, an investigator-initiated multicenter, international randomized controlled trial.
Eligible patients enroll the extension study after the last visit in de TASMA study, the 24th week following the last BT treatment.

The local doctor will be advised to wean of oral and inhaled steroids if possible at their own discretion. After the last TASMA visit subjects are asked to visit yearly to measure the pre-defined endpoints. Safety will be monitored continuously throughout study participation. Efficacy assessments will we done yearly beginning at 1 year following the last TASMA visit during which patients undergo physical examination, questionnaires, pulmonary function test, health care utilization assessment (number of severe asthma exacerbations, emergency room visits and hospital admissions) and their medication use will be reported.

Next to this, patient recruited in the AMC and UMCG will be additionally asked if they are willing to undergo 1 extra bronchoscopy procedure 2 years after the end of the TASMA study to determine ASM mass in endobronchial biopsies and changes in airway remodeling by OCT.

Study burden and risks

For this study there are no major risks involved. All the study procedures except for the research bronchoscopy, FOT and the provocation test with metacholine are standard asthma care. During these test the patient will be

fully monitored by qualified lung function technicians and a medical doctor according to the hospital SOPs.
In our opinion the balance between risks and discomfort for the patients which is expected to be low and the scientific insights that can be obtained is acceptable.
The optional bronchoscopies will be performed under conscious sedation (midazolam or propofol) to minimize patient discomfort. Previous experiences in research bronchoscopies in severe asthma patients by our group and others have proven these procedures to be safe. To our opinion the burden of the additional bronchoscopies including endoscopic biopsies and OCT imaging is justified by the scientific insights that can be obtained. The long term pathological effects of BT on airway remodelling and ASM mass are unknown, and we believe the current study design is the only way to determine these long-term effects. Theoretically, this information could provide clues to optimize further this relatively new treatment technique.
The benefit of study participation is that BT clinical outcome, including safety and efficacy parameters will be monitored over a period of 5 years. The results of the study can contribute to improved patient selection for BT and further optimize BT treatment and potentially improve BT technology.

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

participation in the TASMA study

Exclusion criteria

participating in another clinical trial involving respiratory intervention which in the opinion of the investigator might interfere with the study

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-08-2015
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO

Date:	14-08-2015

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-10-2016
Application type:	Amendment
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
ClinicalTrials.gov	NCT02225392
CCMO	NL53703.018.15