Effect of Reslizumab on small airways in asthma - RESSAPEA

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29078

Source
NTR

Brief title
RESSAPEA

Health condition

asthma, reslizuamb, small airways, CT-scanning

Sponsors and support

Primary sponsor: Amsterdam University Medical Centre, University of Amsterdam
Source(s) of monetary or material Support: TEVA pharma

Intervention

Outcome measures

Primary outcome

In this study the change from baseline in regional image (HRCT) based hyperinflation (iVlobes) and in iVaw after 12 weeks treatment with reslizumab compared to changes in the placebo group

Secondary outcome

iRaw, air trapping, internal lobar airflow distribution, low attenuation or emphysema score, blood vessel density, airway wall thickness. Also correlations between changes in HRCT parameters and SGRQ socire, AQLQ score, FEV1/FVC, FVC, FRC, RV/TLC, FeNO and sputum eosinophils will be assessed.

Study description

Background summary

Patients with severe asthma have a high disease burden because their disease remains poorly controlled despite high doses of inhaled asthma medications or even chronic oral corticosteroids. For these patients novel anti-inflammatory therapies have recently become available. Reslizumab is a humanized monoclonal antibody against interleukin-5, which has been shown efficacy in patients with severe eosinophilic asthma. The exact underlying pathophysiologic mechanism of reslizumab effects is unclear, but might be due to reduced inflammation and improved patency of the small airways with subsequent reduction in air trapping and dynamic hyperinflation. In the present study we will investigate in a randomized double blind placebo controlled trial the effect of 3 months reslizumab treatment on the volume of trapped air, measured by an innovative imaging technique in patients with severe eosinophilic asthma (blood eosinophils > 0.4 x 10E9/L)

Study objective

We hypothesize that the beneficial effetc of Reslizuamb in patients with severe eosinophilic asthma is primarily explained by improvement in small airways function and associated air trapping

Study design

screening, baseline visit (t=0), visit 2 (t=4 wk), visit 3 (t=8 wk), end of study visit (t=12 wk)

Intervention

Patients will recieve reslizuamb (n=21) or placebo (n=11) administered intravenously every 4 weeks for 12 consecutive weeks

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

Patients will be aged 18 - 75 years and have a confirmed diagnosis of severe eosinophilic asthma according to ERS/ATS guidelines. All patients will show persistent blood eosinophilia of >0.4 x 10E9/L despite treatment with high doses of inhaled corticosteroids (>1000 ug/day fluticasone equivalent), or >0.15 x 10E9/L despite chronic oral corticosteroid treatment

Exclusion criteria

• Current smokers or former smokers with a smoking history of ≥15 pack years. A former smoker is defined as a subject who quit smoking at least 6 months prior to Visit 1

• Chronic pulmonary disorders other than asthma

• Chronic diseases other than asthma that are not controlled

• Current malignancy or previous malignancy in remission <12 months

• Monoclonal Antibodies other than Xolair to treat inflammatory disease within 3 hall-lives of visit 1

• Any other condition that, according to the investigator, may affect the outcome of the study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2018
Enrollment:	33
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-09-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55433
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7287
NTR-old	NTR7496
CCMO	NL63056.018.18
OMON	NL-OMON55433

Study results