Effect of Reslizumab on small airways in asthma. RESSAPEA

Published: 06-06-2018
Last updated: 15-05-2024

To investigate the effect the effect of a 3-months treatment with Reslizumab on small airways function in patients with severe eosinophilic asthma, and to relate the changes in small airway function to changes in asthma symptoms and quality of life...

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

Summary

ID

NL-OMON55433

Source
ToetsingOnline

Brief title
RESSAPEA

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Asthma; air trapping

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Aan de farmaceut TEVA B.V. zal om ondersteuning worden gevraagd ter vergoeding van de medicatie,TEVA Pharma

Intervention

Keyword: Air trapping, Astma, Biological, CT-scan

Outcome measures

Primary outcome

in this study is the change from baseline in regional image based hyperinflation (iVlobes) and in iVaw after 3 months Reslizumab treatment 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 and aerosol deposition concentrations, Also correlations between changes in HRCT parameters and patient-reported outcomes, FEV1/FVC, FVC, FRC, RV/TLC, FeNO will be assessed.

Study description

Background summary

Reslizumab is an approved humanized monoclonal antibody developed to target interleukin-5 (IL-5). IL-5 is a key cytokine shown to play a crucial role in the maturation, activation and survival of eosinophils. Increased levels of eosinophils in the sputum an blood have been shown to positively correlate with disease severity and increased risk of asthma exacerbations. Reslizumab acts by binding circulating IL-5 and preventing it from interacting with its receptor. Clinical studies have shown that Reslizumab significantly reduced the rate of asthma exacerbations and improved lung function and quality of life in a specific group of patients with elevated eosinophil levels. However, the mechanism of Reslizumab action in asthma has not been definitively established. We hypothesized that the beneficial effect of Reslizumab in patients with severe eosinophilic asthma is primarily explained by improvement in small airways function and associated air trapping.

Study objective

To investigate the effect the effect of a 3-months treatment with Reslizumab on small airways function in patients with severe eosinophilic asthma, and to relate the changes in small airway function to changes in asthma symptoms and quality of life.

Study design

This is a double-blind, randomized, placebo-controlled single centre intervention study in patients with severe eosinophilic asthma . Patients will be randomized according to a 2:1 schedule. The total number of participants will be 33. (11 patients in the placebo arm and 22 patients in the active arm).

Intervention

Patients will receive Reslizumab (n=22) or placebo (n=11) administered intravenously every 4 weeks for 3 consecutive months.

Study burden and risks

Intravenous administration of Reslizumab has a small risk of hematoma. This will be reduced by the fact that we will work with trained and capable healthcare professionals.
To our opinion the burden of all pulmonary function test will be the same compared with the same tests patients are performing during a standard of care session.
For this study we consider the patients will be on moderate risk.
HRCT scans will be performed at screening and at the end of the study. Although this will be an extra burden for the patients, the risks can be compared with two normal X-rays..
With the information collected during the study it will be possible to evaluate whether or not small airways dysfunction predicts a positive response to anti IL-5 treatment, which will contribute to improved therapy in patients with severe asthma

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam-Zuidoost 1105 AZ

NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam-Zuidoost 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

severe asthma; Blood eosinophil counts >=0.4 x 10E9/L despite adequate treatment with high doses of inhaled corticosteroids (>1000mcg/day fluticasone equivalent)

Exclusion criteria

Subjects with other conditions that could lead to elevated eosinophils such as Hyper eosinophilic Syndromes, including Churg-Strauss Syndrome, or Eosinophilic Esophagitis.
malignancies; use of other monoclonals (except omalizumab)

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-11-2018
Enrollment:	33
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Reslizumab
Generic name:	Cinqaero
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	06-06-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-08-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-02-2019

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-12-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-01-2021
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

ID: 29078
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2017-003958-16-NL
ClinicalTrials.gov	NCT28884
CCMO	NL63056.018.18
OMON	NL-OMON29078