Effect of Reslizumab on small airways in asthma - RESSAPEA

Gepubliceerd: 25-09-2018 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29078

Bron
NTR

Verkorte titel
RESSAPEA

Aandoening

asthma, reslizuamb, small airways, CT-scanning

Ondersteuning

Primaire sponsor: Amsterdam University Medical Centre, University of Amsterdam
Overige ondersteuning: TEVA pharma

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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)

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2018
Aantal proefpersonen:	33
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-09-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55433
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten