An exploratory study to assess the effect of benralizumab on small airway obstruction in patients with severe asthma using functional respiratory imaging

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The aim of this study is to use Functional Respiratory Imaging (FRI) as a biomarker to get a deeper insight into regional changes in the distal bronchial and central bronchial airways of asthmatic patients on benralizumab treatment.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26915

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

asthma

Ondersteuning

Primaire sponsor: Ciro
Overige ondersteuning: Astra Zeneca

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of this study is to investigate the effect (and the onset of this effect) of benralizumab on specific Functional Respiratory Imaging parameters in patients with severe eosinophilic asthma after 4 and 12 weeks treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

Benralizumab has been demonstrated to be an effective therapy for patients with severe eosinophilic asthma (SEA) as it reduces annual exacerbation rates and maintenance oral corticosteroid (OCS) doses and improves pulmonary function. This treatment has been accepted as standard care. Not all patients are responders to this therapy. There are no studies available looking at the locoregional effects on the small airways. The aim of this study is getting locoregional insights by using Functional respiratory Imaging (FRI), this could be helpful in choosing the most adequate treatment approach.

Doel van het onderzoek

The aim of this study is to use Functional Respiratory Imaging (FRI) as a biomarker to get a deeper insight into regional changes in the distal bronchial and central bronchial airways of asthmatic patients on benralizumab treatment.

Onderzoeksopzet

The objectives will be evaluated at baseline, after 4 and 12 weeks of treatment. High Resolution Computed Tomography (HRCT) scans are taken at two different lung volumes, i.e. TLC and FRC. Other objectives are measured by lung function, blood eosinophil count, questionnaires (dyspnoea) and exercise tolerance by 6MWT.

Contactpersonen

Publiek

CIRO
bita hajian

0031639804621

Wetenschappelijk

CIRO
bita hajian

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients eligible for treatment with benralizumab will be aged 18 - 75 years and have a confirmed diagnosis of severe eosinophilic asthma according to ERS/ATS guidelines.
Pre-bronchodilator FEV1 of 80% predicted and history of physician-diagnosed asthma requiring treatment with medium-to-high dose ICS (>250µg fluticasone dry powder formulation equivalents total daily dose) and a LABA, for at least 12 months prior to Visit 1.
All patients will show persistent blood eosinophilia of >0.3 x 10E9/L despite treatment with high doses of inhaled corticosteroids (>500 ug/day fluticasone equivalent), or >0.15 x 10E9/L despite chronic oral corticosteroid treatment at baseline.
At least 2 documented asthma exacerbations in the 12 months prior to the date informed consent.
Females of childbearing potential must have a negative pre-treatment urine pregnancy test.
Subjects are allowed to use their own inhalation therapy during this study.
Subjects who are steroid dependent and maintained on an equivalent of ≤10 mg oral prednisone per day for at least 3 months prior to Visit 1 are eligible, providing the dose of oral steroids remains stable during the run-in period.

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
Current malignancy or previous malignancy in remission <12 months
Prior use of anti IL5 or anti IL5 Receptor monoclonal Antibodies. For patients treated with omalizumab there is a wash out period of 3 month.
Any other condition that, according to the investigator, may affect the outcome of the study

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2021
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9103
Ander register	METC AzM : METC

Resultaten