Evaluation treatment with biologicals in severe asthma

Gepubliceerd: 14-10-2017 Laatst bijgewerkt: 18-08-2022

In patients with severe asthma identification of patient characteristics, biomarkers and parameters can be helpful for response evaluation in treatment with biologicals.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24843

Bron
NTR

Aandoening

severe asthma, biological

Ondersteuning

Primaire sponsor: Medical Centre Leeuwarden
Overige ondersteuning: Stichting Longgeneeskunde Fryslan

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Patient characteristics / biomarkers as predictors of response in treatment with biologicals in severe asthma

Toelichting onderzoek

Achtergrond van het onderzoek

A lot of patients with severe asthma are treated in severe asthma centres with biologicals and it is expected that the amount of these patients will increase. These patients are systematically evaluated at the onset of the treatment and at 2 and 4 months after starting. After 4 months most of the patients can be evaluated as a responder or non-responder and responders continue their treatment with a systematical follow-up. However, (non) responding is partly based on subjective judgement of the patient and clinician, and on the improvement of miscellaneous parameters. Yet, which patient characteristics are predictors of response and which parameters are the most useful for response evaluation is still unravelled. Likewise, there is a lack of knowledge about the variation in time to response between the patients. Finally, the registration studies of the biologicals showed a good effect after 6 months of treatment, but there are little data on longterm effects. So the optimal use of biologicals is still questioned. In this study we hope to unravel these questions and give answers for optimal treatment with biological in the daily practice.

Doel van het onderzoek

In patients with severe asthma identification of patient characteristics, biomarkers and parameters can be helpful for response evaluation in treatment with biologicals.

Onderzoeksopzet

The study consist of a baseline visite, visit at 2 and 4 months, and follow-up during continuing biological treatment.

At baseline, 2, 4 months and continuing fase parameters as part of the clinical proces are registered: demographics and patient characteristics, prednisolone and inhaled corticosteroids doses, adverse events, questionnaires (ACQ, AQLQ, HCU, BORG-ENT symptoms), lungfunction (spirometry, FeNO), blood sampling (cel differentation, IgE, RAST).

Onderzoeksproduct en/of interventie

Prospective evaluation of patients with severe asthma treated with biologicals.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with severe asthma treated with biologicals

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-

Onderzoeksopzet

Opzet

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

Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2016
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-10-2017
Soort:	Eerste indiening

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	NL6580
NTR-old	NTR6754
Ander register	: nWMO 245

Resultaten

Samenvatting resultaten
N/A