The real-world oral corticosteroid burden in patients starting anti-interleukin-5 therapy

Gepubliceerd: 06-11-2020 Laatst bijgewerkt: 18-08-2022

There is a large difference in long term OCS use between before anti-IL-5 and after antil-IL-5 therapy

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

Samenvatting

ID

NL-OMON28832

Bron
Nationaal Trial Register

Verkorte titel
ROSA

Aandoening

Severe eosinophilic astma

Ondersteuning

Primaire sponsor: Medical Center Leeuwarden
Overige ondersteuning: MCL

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in cumulative OCS dose between 2 years before and 2 years after start of anti-IL-5

therapy

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Currently, three biologics targeting the IL-5 pathway (mepolizumab, reslizumab and benralizumab) are approved for the treatment of severe eosinophilic asthma. Oral corticosteroid (OCS) dose reduction is an important treatment goal of these new drugs, in order to reduce OCS-related side effects.
Phase 3 trials have shown the OCS-sparing effect of mepolizumab and benralizumab, with significant reductions in median daily OCS dose after 6 months of treatment. Yet, data on the long-term cumulative OCS-dose before and after anti-IL-5 treatment initiation in a real-world population are lacking. Insight in the biologic-induced effects on this long-term OCS burden may provide further awareness on the achieved effects of anti-IL-5 therapy and add in the justification of the application of expensive biological therapy for severe asthma.
Objective: To study the change in cumulative OCS dose between 2 years before and 2 years after anti-IL-5 initiation in severe eosinophilic asthma.
Study design: Observational, retrospective cohort study.
Study population: Patients in the national RAPSODI registry, receiving anti-IL-5 therapy in the treatment of severe asthma before 1/1/2019.
Main study parameters/endpoints:
The main study parameter is the cumulative OCS dose (mg) and change in this cumulative dose in the two years before and after initiating anti-IL-5 therapy for severe asthma.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The selected patients are already included in the RAPSODI registry and treated for their severe asthma. The current study does not have an intervention. Therefore, the burden and risks associated with participation are non-existent.

Doel van het onderzoek

There is a large difference in long term OCS use between before anti-IL-5 and after antil-IL-5 therapy

Onderzoeksopzet

For the selected patients, the startdate of anti-IL-5 therapy will be determined. The change in cumulative OCS dose between 2 years before and 2 years after start of anti-IL-5 therapy will be determined retrospectively by collecting communal pharmacy data.
The course of the mean OCS dose per 3 month periods, during 2 years before and after initiating anti-IL-5 treatment will be determined by splitting the gathered pharmacy data in trimesters, retrospectively.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Included in RAPSODI, receiving anti-IL-5 treatment before 1/1/2019.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Inflammatory comorbidities (Rheumatoid disease, inflammatory bowel disease or oncological disease) (based on registration in RAPSODI)

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 gestart
(Verwachte) startdatum:	05-10-2020
Aantal proefpersonen:	350
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	06-11-2020
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	NL9041
Ander register	RTPO te Leeuwarden : nWMO 20200065

Resultaten