HOme Administration of Monoclonal antibodies: an Evaluation by Severe asthma patients

Gepubliceerd: 17-06-2019 Laatst bijgewerkt: 18-08-2022

Home administration of monocolonal antibodies for severe asthma improves patient satisfaction

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

Samenvatting

ID

NL-OMON27883

Bron
Nationaal Trial Register

Verkorte titel
HOMES

Aandoening

Severe asthma

Ondersteuning

Primaire sponsor: No
Overige ondersteuning: No

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Patient satisfaction

Toelichting onderzoek

Achtergrond van het onderzoek

Background
Increasing numbers of patients with severe asthma are treated with biologicals (monoclonal antibodies) (anti IL-5, anti IgE, anti IL-4/IL-13). Currently these biologicals are administrated in the hospital (day care). Recently some of the biologicals are approved for home administration. Existing research, concerning home treatment for other chronic diseases, suggests improved patient satisfaction. We aim to evaluate home treatment of biologicals for severe asthma in an observational (before-after) study in three tertiary severe asthma centres in the Netherlands.

Objective:
1.To evaluate patient experience and satisfaction in home treatment with biologicals for severe asthma compared to in hospital treatment.
2. To compare two different strategies in starting home treatment with biologicals for severe asthma.
Both groups will start treatment with biologicals in hospital day care for the first 4 months. After evaluating response to therapy;
a. group 1: Patients start direct independent self-administration at home for 8 months.
b. group 2: Patients are supported by a specialized nurse for the first 4 months of home treatment, followed by self-administration for the remaining study period.
(Reslizumab will be supported by a nurse for the complete study period, because of the intravenous administration)
2. To evaluate the efficiency of home treatment compared to in hospital treatment (based on motivation, self-management behaviour and health care utilisation of severe asthma patients and the practical feasibility and costs of the home treatment service provided by the hospitals).

All patients are trained on drug administration and observed for appropriate technique, following a standardized education protocol, before home therapy.

Doel van het onderzoek

Home administration of monocolonal antibodies for severe asthma improves patient satisfaction

Onderzoeksopzet

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Contactpersonen

Publiek

HAGA Ziekenhuis
Saar Van Nederveen-Bendien

0031639592319

Wetenschappelijk

HAGA Ziekenhuis
Saar Van Nederveen-Bendien

0031639592319

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria
- >18 yr
- Valid criteria for starting treatment with biologicals for severe asthma, according to international guidelines (ERS/ATS)
- Home treatment will only be started when a positive response to therapy is found, during the first evaluation after four months

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

No

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	17-06-2019
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	17-06-2019
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	NL7807
Ander register	METC ZWH : METCZWH 19-030

Resultaten