Monopoly - predicting clinical benefit of dupilumab in adult patients with chronic rhinosinusitis with nasal polyps (CRSwNP)

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Therapeutic responders of dupilumab for CRSwNP have a different endo- and phenotype substrate of the type-2 inflammation than slow or poor responders as can be assessed by peripheral blood and nasal polyp tissue.

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

Samenvatting

ID

NL-OMON24913

Bron
NTR

Verkorte titel
N/A

Aandoening

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Ondersteuning

Primaire sponsor: Amsterdam UMC, location AMC
Overige ondersteuning: Amsterdam UMC, location AMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To identify predicting phenotypical and endotypical biomarkers for the response to dupilumab in adult patients with CRSwNP, by comparing the type 2 inflammation in the peripheral blood and nasal polyp tissue at baseline and after 6 months of treatment with dupilumab between responders and non-responders

Toelichting onderzoek

Achtergrond van het onderzoek

Observational exploratory study of 91 consecutively included adult patients (≥ 18 years) treated with dupilumab for their CRSwNP as indicated by the ruling guideline EPOS2020. We compare the type-2 inflammation in peripheral blood an nasal polyps at baseline and after 6 months of therapeutic responders with poor responders by histochemical and single cell suspension flow cytometry analysis. The study aims to: 1) identify predicting phenotypical and endotypical biomarkers for the therapeutic response to dupilumab; and 2) define phenotypical differences in the peripheral blood and nasal polyp ILC2s, eosinophils, basophils, and mast cells between responders and poor responders. Therapeutic response is assessed by questionnaires and clinical parameters.

Doel van het onderzoek

Therapeutic responders of dupilumab for CRSwNP have a different endo- and phenotype substrate of the type-2 inflammation than slow or poor responders as can be assessed by peripheral blood and nasal polyp tissue.

Onderzoeksopzet

Materials: baseline, 6 months.
Questionnaires: baseline, 1, 2, 3 and 6 months.

Onderzoeksproduct en/of interventie

No therapeutic interventions. Extra blood withdrawal during standard baseline and 6 months check-up phlebotomy and biopsy of nasal polyp tissue at baseline and 6 months.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

adult patients (≥ 18 years) with CRSwNP with an indication for biological treatment as per the ruling European guideline EPOS2020 who will be treated with dupilumab

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• age ≤ 17 years
• patient is not able to complete the SNOT 22 questionnaire
• strong indication for surgical treatment (e.g.: mucoceles)
• systemic diseases affecting the nose (e.g.: GPA, EGPA, sarcoid, primary ciliary dyskinesia, cystic fibrosis)
• antrochoanal polyps (isolated benign polyps originating from the mucosa of the maxillary sinus with a distinctive small stalk)
• inverted papilloma and malignant polyps
• acute upper or lower respiratory tract infections within 2 weeks before the inclusion visit
• use of systemic corticosteroids within 4 weeks before the inclusion visit
• need for continuous systemic corticosteroid treatment for other disease than CRSwNP
• systemic diseases preventing participation in the study (all comorbidities that have a higher impact on quality of life than CRSwNP and/or making the patient at risk during the study period)
• other systemical medical treatments influencing disease or primary and secondary study outcome measurements such as (non-)selective immunosuppressants (e.g.: azathioprine, methotrexate) and other monoclonal antibodies other than dupilumab (e.g.: adalimumab)

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:	01-01-2021
Aantal proefpersonen:	91
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	26-02-2021
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	NL9302
Ander register	METC AMC : METC 2020_254

Resultaten

Samenvatting resultaten
N/A