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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24913

Source
NTR

Brief title
N/A

Health condition

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Sponsors and support

Primary sponsor: Amsterdam UMC, location AMC
Source(s) of monetary or material Support: Amsterdam UMC, location AMC

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

To define phenotypical differences in the peripheral blood and nasal polyp ILC2s, eosinophils, basophils, and mast cells between responders and non-responders to dupilumab

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

• 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)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2021
Enrollment:	91
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	26-02-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9302
Other	METC AMC : METC 2020_254

Study results

Summary results
N/A