Assessing long-term outcomes of dupixent treatment in patients with chronic rhinosinusitis with nasal polyposis

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As part of your treatment, you will receive DUPIXENT. We would like to learn what the experiences of patients are with this medical product and if you notice any changes. The aim of the study is to better understand the characteristics of patients…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory and mediastinal neoplasms benign (excl mesotheliomas)
Study type	Observational non invasive

Summary

ID

NL-OMON53573

Source
ToetsingOnline

Brief title
AROMA

Condition

- Respiratory and mediastinal neoplasms benign (excl mesotheliomas)
- Upper respiratory tract disorders (excl infections)

Synonym
Inflammation of the nasal and paranasal sinus mucosa, nasal polyps

Research involving
Human

Sponsors and support

Primary sponsor: Regeneron Pharmaceuticals, Inc.
Source(s) of monetary or material Support: Sponsor;Regeneron Pharmaceuticals;Inc.

Intervention

Keyword: Dupixent, Nasal, Polyposis, Rhinosinusitis

Outcome measures

Primary outcome

• Descriptive summary of symptoms, HRQoL, and change over time

• Descriptive summary of patients and disease characteristics with CRSwNP, and type 2 comorbidities

Secondary outcome

• Descriptive summaries of DUPIXENT and other CRSwNP treatments used during the study, including most commonly used treatments, dosage, adherence, interruption, place, and frequency of administration (home or clinic)

• Reasons for initiation of new CRSwNP treatment(s), concomitant therapies, treatment durations, and reasons for discontinuation and/or switching

• Global assessment of disease severity and treatment satisfaction (patient and physician)

• Descriptive summary of adverse events

Study description

Background summary

Chronic rhinosinusitis with nasal polyposis (CRSwNP) is a chronic disease of the airways behind the nostrils and sinuses (cavities in the nose that hold mucus) that affect patients (loss of smell, facial pain) and worsens quality of

life. Dupixent has been studied in randomized control trials as an extra treatment to standard of care (nasal steroids) but real world data is needed.

This study will focus on the assessment of the use patterns of DUPIXENT for CRSwNP with details concerning the most common treatment regimens, dosage, place and device of administration, and reason for starting or stopping, as well as switching to other therapies. Finally, this registry study aims to collect long-term safety and effectiveness data on patients with CRSwNP treated with DUPIXENT. This data will help the development for a better treatment against CRSwNP.

Study objective

As part of your treatment, you will receive DUPIXENT. We would like to learn what the experiences of patients are with this medical product and if you notice any changes. The aim of the study is to better understand the characteristics of patients who receive DUPIXENT for CRSwNP and the treatment patterns used in a real-world setting. The study will also collect data on the long-term effectiveness and safety of DUPIXENT. DUPIXENT is approved in multiple countries for specific indications and age ranges to treat patients with atopic dermatitis, asthma, and/or chronic rhinosinusitis with nasal polyps. Your study physician can provide more detailed information regarding approved indications in your country.

You have been prescribed DUPIXENT by your doctor, because it is necessary for your treatment and not in the context of this investigation. That means that you can collect the medical product at your own pharmacy and possibly have to pay the normal personal contribution.

Study design

Assessing long-teRm Outcomes of dupiluMAb (AROMA) is a global, prospective, observational, multicenter, real world study to characterize the safety and effectiveness of DUPIXENT by evaluating objective findings and patient-reported outcomes (PROs) in patients with CRSwNP. It will expand on the data from prior randomized clinical studies and aims to fill the knowledge gaps noted in the objectives in a real-world setting.

Study burden and risks

It is an observational questionnaire study without intervention. There is no risk for the patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients >=18 years at initiation
2. All patients who are newly initiated on DUPIXENT for the treatment of CRSwNP according to the respective prescribing information (Product Label or SmPC)
3. Willing and able to comply with clinic visits and study-related procedures as per protocol
4. Provide informed consent signed by study patient or legally acceptable representative
5. Able to understand and complete study-related questionnaires as per protocol

Exclusion criteria

1. Patients who have a contraindication to DUPIXENT according to the country specific prescribing information
2. Any previous treatment with DUPIXENT for any condition
3. Any condition that, in the opinion of the investigator, may interfere with the patient*s ability to participate in the study, such as short life expectancy, substance abuse, severe cognitive impairment, or other medical, social, or personal conditions and circumstances that can predictably prevent the patient from adequately completing the schedule of visits and assessments
4. Participation in an ongoing interventional or observational study that might, in the treating physician*s opinion, influence the assessments for the current study*

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-06-2023
Enrollment:	39
Type:	Actual

Ethics review

Approved WMO Date:	25-05-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	31-10-2022

Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	08-06-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	02-04-2024
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	14-01-2025
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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
ClinicalTrials.gov	NCT04959448
CCMO	NL80896.028.22