A multicenter, randomized, double-blind, parallel-group, placebo-controlled study of fevipiprant once daily plus standard-of-care (SoC) for assessment of the efficacy in reduction of nasal polyps size in patients with nasal polyposis and concomitant asthma

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital respiratory tract disorders
Study type	Interventional

Summary

ID

NL-OMON48110

Source
ToetsingOnline

Brief title
CQAW039A2322 (THUNDER)

Condition

- Congenital respiratory tract disorders

Synonym
polyps in the nose, respiratory disease

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Novartis Pharma B.V. (verrichter/sponsor van het onderzoek).

Intervention

Keyword: asthma, fevipiprant, nasal polyposis

Outcome measures

Primary outcome

In patients with nasal polyps with a polyp size score * 4 at baseline, to demonstrate a difference in mean change from baseline in polyp size at Week 16, measured by the nasal polyp score (NPS, assessed by nasal endoscopy with central reading), between fevipiprant (150 mg or 450 mg once daily, separately) and placebo.

Secondary outcome

- To evaluate the effect on symptoms as measured by the nasal congestion score (NCS) with fevipiprant (150 mg or 450 mg once daily), compared with placebo following 16 weeks of treatment
- To evaluate the effect on quality of life as measured by the Sino-Nasal Outcome Test - 22 (SNOT-22) with fevipiprant (150 mg or 450 mg once daily), compared with placebo following 16 weeks of treatment.
- To evaluate the effect on Smell as measured by the university of Pennsylvania smell identification test (UPSIT) with fevipiprant (150 mg or 450 mg once daily), compared with placebo following 16 weeks of treatment.

- To evaluate the effect of fevipiprant 150 mg and 450 mg compared with placebo

in terms of general safety/tolerability following 16 weeks of treatment.

Study description

Background summary

QAW039 is a DP2 competitive antagonist in investigation in severe asthma. It exerts its effect by binding to DP2 receptors on white blood cells (like eosinophils) reducing inflammation. Inflammation in the lungs can lead to narrowing of the airways and asthmasymptoms, like wheezing and shortness of breath. In the same way inflammation of the sinuses can be caused. Inflammation of the sinuses can cause nasal polyps.
In this study we want to investigate the safety and efficacy of QAW039 (fevipiprant) in the treatment of patients with nasal polyps and asthma. We want to investigate if QAW039 can reduce the size of the nasal polyps and reduce symptoms due to the nasal polyps, like less symptoms of stuffy nose, and/or stuffy sinuses, improvement of quality of life and better smell.

Study objective

The purpose of this study is to evaluate the efficacy and safety of fevipiprant 150 mg and 450 mg compared to placebo in the reduction of nasal polyps size and the effect on symptoms, quality of life and smell via patient-reported outcomes in patients with nasal polyposis and concomitant asthma.

Study design

This is a Phase 3b, Proof-of-concept study with a randomized, multicenter, doubleblind, placebo-controlled, parallel-group study design to determine the ability of fevipiprant plus SoC compared to placebo plus SoC to reduce the size of NPs. The study will include: Screening period of 2 weeks to assess eligibility; Run-in period of 4 weeks where patients will utilize mometasone furoate spray (200 *g once daily, administered as two 50 *g actuations into each nostril); Treatment period of 16 weeks (with visits held every month for study procedures) and a Follow-up period of 2 weeks following the last dose of study drug to collect additional data for safety variables. Patients will continue to use the mometasone furoate SoC throughout the treatment period.

Intervention

- QAW039 150 mg and QAW039 450 mg once daily

- Matching placebo to QAW039 150 mg and QAW039 450 mg once daily

Study burden and risks

Possible risks of participation in this study are any side effects of QAW039, the time investment and extra assesments. See protocol, investigator's Brochure and the ABR form.

Contacts

Public
Novartis

Raapopseweg 1
Arnhem 6824 DP
NL
Scientific
Novartis

Raapopseweg 1
Arnhem 6824 DP
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients aged 18 years or more with a diagnosis of nasal polyps with Nasal polyp score 4 or more with minimum score of 2 in each nostril.

- Concomitant diagnosis of asthma for a period of at least 6 months prior to screening.
- Patients on stable asthma treatment of at least inhaled corticosteroids(any dose) alone for at least 6 months prior to screening or ICS for 6 months prior to screening with any required, inhaled medication (LABA, LAMA) added at least 6 weeks prior to screening.

Exclusion criteria

- Asthma exacerbation, within 6 weeks prior to screening, that required systemic corticosteroids, hospitalization or emergency room visit.
- Chronic/maintenance use of oral corticosteroids (OCS) defined as any continuous use of OCS for a period of 1 month or more, within 1 year of screening.
- Use of biologics for asthma or any other indications, that has the potential to interfere/affect either asthma or nasal polyposis disease progression, within 6 months of screening.
- Use of medication for sino-nasal symptoms (antibiotics with or without OCS) within 30 days of screening or during the run-in period.
- Use of tetracycline or macrolide antibiotics specifically, within 8 weeks of screening.
- History of nasal surgery modifying the structure of the nose such that assessment of the nasal polyp score is not possible.
- Patients with baseline ACQ-5*1.5.
- Patients receiving any medications in the classes listed in Table 6-1. Prohibited Medication should be excluded unless they meet the criteria as specified in Table 6-1.
- Patients on >20 mg of simvastatin, > 40 mg of atorvastatin, >40 mg of pravastatin, or >2 mg of pitavastatin 7 days prior to run-in visit. Statin doses less than or equal to these doses as well as other statins will be permitted during the study.
- Patients on any statin therapy with a CK level >2 X ULN at Screening Visit

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-04-2019
Enrollment:	7
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	QAW039
Generic name:	fevipiprant

Ethics review

Approved WMO Date:	28-11-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-12-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-01-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	05-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
Other	NCT03681093
EudraCT	EUCTR2018-002073-22-NL
CCMO	NL67625.018.18