ForPatients
by Roche

Nasal Polyps

A Clinical Trial of Omalizumab in Participants With Chronic Rhinosinusitus With Nasal Polyps

Trial Status	Trial Runs In	Trial Identifier
Completed	10 Countries	NCT03280537 2017-001718-28 GA39855

The clinical trial information herein is sourced from public registries such as ClinicalTrials.gov, EuClinicalTrials.eu, and ISRCTN.com. Additional patient-friendly (lay) content has been prepared by Roche to support understanding.

Official Title:

A Phase III, Randomized, Multicenter, Double-blind, Placebo-controlled Clinical Trial of Omalizumab in Patients With Chronic Rhinosinusitis With Nasal Polyps

Trial Summary:

The purpose of this study is to determine the efficacy and safety of omalizumab compared with placebo in adult patients with chronic rhinosinusitis with nasal polyps (CRSwNP) who have had an inadequate response to standard-of-care treatments. Study GA39688 (POLYP 1; NCT03280550) was another Phase III study by the Sponsor with identical objectives and design and was run in parallel with this study.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT03280537 2017-001718-28 GA39855
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years & # 75 Years	No

Inclusion Criteria:

- Age 18-75 years, inclusive, at time of signing Informed Consent Form.
- Ability to comply with the study protocol, in the investigator's judgment.

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- Nasal polyp score (NPS) >= 5, with a unilateral score of >= 2 for each nostril, at screening (Day -35), and on Day -7.
- Sino-Nasal Outcome Test-22 (SNOT-22) score >=20 at screening (Day -35) and at randomization (Day 1).
- Treatment with at least nasal mometasone 200 micro gram per day, or equivalent daily dosing of nasal corticosteroid (CS), for at least 4 weeks before screening (Day -35).
- Treatment with nasal mometasone 200 micro gram twice a day (BID) (or once a day [QD] if intolerant to twice daily) during the run-in period with an adherence rate of at least 70%.
- Presence of nasal blockage/congestion with NCS >=2 (1-week recall) at Day -35 and an average of the daily NCS score over the 7 days prior to randomization of NCS >1 with at least one of the following symptoms prior to screening: nasal discharge (anterior/posterior nasal drip) and/or reduction or loss of smell.
- Eligibility per the study drug dosing table
- Willingness to maintain all background medications stable for the duration of the treatment and follow-up periods.
- Willingness and ability to use electronic device to enter study-related information in electronic devices (electronic diary [eDiary]/electronic tablet [eTablet]).
- Demonstration of at least 70% adherence to eDiary daily symptom assessment during run in period, with fully completed entries on at least 4 days in the week prior to randomization.
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use acceptable contraceptive methods during the treatment period and for 60 days after the last dose of study drug.

Exclusion Criteria:

- Known history of anaphylaxis/hypersensitivity to omalizumab.
- Treatment with investigational drugs within 12 weeks or 5 half-lives (whichever is longer) prior to screening (Day -35).
- Treatment with monoclonal antibodies (e.g., omalizumab, mepolizumab) for 6 months prior to screening (Day -35).
- Current treatment with leukotriene antagonists/modifiers, unless participant has been on stable dosing of such medication for at least 1 month prior to screening (Day -35).
- Treatment with non-steroid immunosuppressants within 2 months or 5 half-lives, whichever is longer, prior to screening (Day -35).
- Treatment with systemic corticosteroids, except when used as treatment for nasal polyposis, within 2 months prior to screening (Day -35).
- Usage of systemic CS during the run-in period. Participants requiring systemic CS during run-in may be rescreened after completing systemic CS.
- Treatment with intranasal CS drops or CS administering devices (e.g., OptiNose device or stents) within 1 month prior to screening (Day -35) or during the run-in period.
- History of nasal surgery (including polypectomy) within 6 months prior to screening.
- History of sinus or nasal surgery modifying the structure of the nose such that assessment of NPS is not possible.
- Uncontrolled epistaxis requiring surgical or procedural intervention, including nasal packing, within 2 months prior to screening.
- Known or suspected diagnosis of cystic fibrosis, primary ciliary dyskinesia (e.g., Kartagener syndrome) or other dyskinetic ciliary syndromes, hypogammaglobulinemia or other immune deficiency syndrome, chronic granulomatous disease and granulomatous vasculitis, granulomatosis with polyangiitis (e.g., Wegener's Granulomatosis), or eosinophilic granulomatous with polyangiitis (EGPA) (e.g., Churg-Strauss syndrome).
- Presence of antrochoanal polyps.
- Concomitant conditions that interfere with evaluation of primary endpoint:

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- Nasal septal deviation occluding one or both nostrils. * Ongoing rhinitis medicamentosa. * Acute sinusitis, nasal infection, or upper respiratory infection during the run-in period. * Known or suspected invasive or expansive fungal rhinosinusitis.
- Known HIV infection at screening.
- Known acute and chronic infections with hepatitis C virus (HCV) and hepatitis B virus (HBV) at screening.
- History of myocardial infarction, unstable angina, cerebrovascular accident, or transient ischemic attack or a known history of a hypercoagulable disorder
- Active tuberculosis requiring treatment within 12 months prior to screening (Day -35).
- Initiation of or change in allergen immunotherapy within 3 months prior to screening (Day -35) or during the run-in period.
- Initiation of or change in aspirin desensitization within 4 months prior to screening (Day -35) or during the run-in period.
- Pregnant or breastfeeding, or intending to become pregnant during the study or within 60 days after the last dose of omalizumab.
- Current malignancy or history of malignancy within 5 years prior to screening, except for appropriately treated carcinoma in situ of the cervix or non-melanoma skin carcinoma that has been treated or excised and is considered resolved.
- Any serious medical condition (including but not limited to significant arrhythmia, uncontrolled hypertension, significant pulmonary disease other than asthma) or abnormality in clinical laboratory tests that precludes the participant's safe participation in and completion of the study.
- History of alcohol, drug, or chemical abuse within 6 months of screening.

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