

# Omalizumab for Asthma with Non-detectable Sensitization to an Aeroallergen

Published: 07-01-2016

Last updated: 19-04-2024

To assess the immunological efficacy of four-month treatment of omalizumab in patients with non-atopic asthma compared to patients with allergic asthma

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Bronchial disorders (excl neoplasms)
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON42417

### Source

ToetsingOnline

### Brief title

OMANSA

### Condition

- Bronchial disorders (excl neoplasms)

### Synonym

Asthma

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Asthma, Atopic, non-atopic, Omalizumab

## Outcome measures

### Primary outcome

The main study endpoint is the expression levels of Fc\*RI on basophils before and after four-month omalizumab treatment.

### Secondary outcome

Clinical evaluation

- \* Spirometry (FEV1, VC, FVC)
- \* Lung Volumes (RV, TLC, ITGV)
- \* Asthma control Questionnaire
- \* Blood eosinophil count
- \* Number of exacerbations experienced during treatment period
- \* Global assessment of treatment efficacy

Immunological parameters

- \* Serum free-IgE levels
- \* Antigen-specific IgE levels
- \* Expression of IgE receptors on PBMC
- \* Dendritic cell markers and function
- \* Serum cytokine levels
- \* Basophil sensitivity
- \* T cell proliferation assays
- \* B cell profiling

# Study description

## Background summary

Omalizumab is a humanized monoclonal anti-IgE antibody used to treat severe allergic asthma. In allergic asthma omalizumab alleviates symptoms by capturing free (total including allergen-specific) IgE molecules and preventing them from binding to IgE receptors on effector cells which would otherwise cause allergen-dependent cell activation and histamine release. Recent studies have shown omalizumab to be clinically effective in treating patients with severe asthma without detectable allergic asthma, however, the mechanism behind the efficacy of this drug in these patients is not clear.

## Study objective

To assess the immunological efficacy of four-month treatment of omalizumab in patients with non-atopic asthma compared to patients with allergic asthma

## Study design

single center, observational study

## Study burden and risks

Patients will be treated with Omalizumab initiated by the department of pulmonology at the LUMC. During the first visit information regarding medical history and demography will be obtained. Nasal flush samples (5ml) and blood samples (70 ml) will be collected at entry and after the four-month treatment period. Patients will undergo pulmonary function tests and will be required to complete the Asthma Control Questionnaire (ACQ) and before and after the treatment period. The physician will perform a Global Evaluation of Treatment Efficacy (GETE). The nasal flush sample collection is specific to this study and is not part of the patient's standard care. All other parameters including venepuncture will be performed regardless of participation in this trial. The burden experienced by the patient consists of additional tubes of blood being collected during the routine venepuncture and the time required to perform the nasal flush (15-20 minutes). There is minimal risk associated with this procedure. Although the patients involved in this study will not benefit directly, the outcome may facilitate improvement of healthcare for asthma patients in the future.

## 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

- \* Initiation of omalizumab therapy as part of the medical treatment, based on the indication of severe or allergic asthma (group 1) or severe non-atopic asthma (group 2).
- \* Serum IgE levels and body weight within current dosing guidelines (Dosing and administration guidelines for XOLAIR.  
<http://www.xolairhcp.com/xolairhcp/dosing-and-administration.html>)
- \* Aged between 18 and 65 years old
- \* Written informed consent

### Exclusion criteria

- \* Clinical diagnosis other than asthma that may interfere with immunological assessments

- \* No initiation of omalizumab treatment
- \* Current or former smokers with a > 10 pack-year history
- \* Treatment of an asthma exacerbation in the 6 weeks prior study entry
- \* Other indications for omalizumab treatment such as ABPA, urticaria, severe food allergies
- \* Pregnancy or breastfeeding
- \* Participation in intervention studies

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status: Will not start

Enrollment: 60

Type: Anticipated

## Ethics review

Approved WMO

Date: 07-01-2016

Application type: First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

## 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

CCMO

### ID

NL54993.058.15