Omalizumab for Asthma with Non-detectable Sensitization to an Aeroallergen

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

Ethical review	Approved WMO
Status	Will not start
Health condition type	Bronchial disorders (excl neoplasms)
Study type	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	ID
CCMO	NL54993.058.15