

# The impact of omalizumab treatment in UK clinical practice for asthma

<b>Submission date</b> 11/04/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/05/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/02/2018	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Allergic asthma is the most common type of asthma, where symptoms such as coughing, wheezing, chest tightness and breathlessness begin when the body reacts to something it is allergic to. Omalizumab is a drug licensed for the treatment of severe allergic asthma. A study has demonstrated that use of omalizumab reduces oral corticosteroid use, hospitalisations and A&E visits, and increases patients' quality of life. In order to follow on from and reinforce the findings from this study, we are now undertaking a further study to collect data from the point of decision to prescribe omalizumab.

### Who can participate?

Patients aged 16 and over who are going to receive at least one dose of omalizumab for the treatment of severe persistent allergic asthma as part of normal clinical care.

### What does the study involve?

Patients are treated as per standard clinical practice with omalizumab, but are also requested to complete a breathing test and questionnaires about asthma and their quality of life after 16 weeks, 8 months and 12 months. There is therefore little deviation from standard omalizumab care from the patients' perspective.

### What are the possible benefits and risks of participating?

Not provided at time of registration.

### Where is the study run from?

Novartis Pharmaceuticals (UK)

### When is the study starting and how long is it expected to run for?

March 2012 to August 2013

### Who is funding the study?

Novartis Pharmaceuticals (UK)

Who is the main contact?

Dr Amr Radwan

## Contact information

### Type(s)

Scientific

### Contact name

Dr Amr Radwan

### Contact details

Novartis Pharmaceuticals UK Ltd  
200 Frimley Business Park  
Frimley  
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## Additional identifiers

### Protocol serial number

CIGE025AGB04

## Study information

### Scientific Title

The impact of omalizumab treatment in UK clinical practice Asthma Patient Experience on Xolair® (Omalizumab) (the APEX II study)

### Acronym

APEX-II

### Study objectives

Null Hypothesis: The initiation of omalizumab in the treatment of severe persistent allergic asthma in normal clinical practice is associated with a difference of less than 25% in the mean daily dose of oral corticosteroids (OCS) per patient in the 12 months post vs the 12 months pre-initiation.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

This observational study will be submitted for NHS REC review. MHRA requirements for spontaneous reporting of adverse events will be met. Patient consent will be sought for research use of medical records. Local management (R&D) approval will be sought to conduct the study at each site.

## Study design

Multicentre observational study

## Primary study design

Observational

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Severe allergic asthma (consistent with the licence for omalizumab).

## Interventions

This study will investigate patients who are prescribed omalizumab treatment as part of routine clinical practice. Retrospective and prospective clinical assessments will be undertaken by a member of the clinical team in routine clinic. Patients will also be asked to complete the Asthma Control Test questionnaire (ACT) and Asthma Quality of Life Questionnaire (AQLQ) at baseline, 16 weeks, 8 months and 12 months post-initiation of omalizumab.

## Intervention Type

Drug

## Phase

Not Applicable

## Drug/device/biological/vaccine name(s)

Omalizumab

## Primary outcome(s)

The difference in the mean (SD) daily dose of OCS per patient in the 12 months pre- versus post-initiation of omalizumab and its 95% confidence interval (CI)

## Key secondary outcome(s)

1. The difference in lung function (FEV1 % predicted) at baseline versus 16 weeks, 8 months and 12 months post-initiation of omalizumab
2. The difference in patient reported outcomes (scales ACT & AQLQ) at baseline versus 16 weeks, 8 months and 12 months post-initiation of omalizumab
3. The difference in mean (SD) NHS secondary care resource utilisation in the 12 months pre-versus the 12 months post-initiation of omalizumab
4. The proportion of patients stopping, the proportion reducing and the proportion stopping OR reducing OCS within 12 months following initiation of omalizumab
5. The correlation coefficient between stopping OCS and change in AQLQ from baseline to 16 weeks, 8 months and 12 months post-initiation of omalizumab
6. The difference in the number of documented asthma exacerbations in the 12 months pre-versus the 12 months post-initiation of omalizumab
7. The correlation coefficient between change in number of exacerbations and change in lung function from baseline to 16 weeks, 8 months and 12 months post-initiation of omalizumab
8. The difference in the number of working/education days lost in the 12 months pre versus the 12 months post-initiation of omalizumab
9. Distribution of concomitant steroid-sparing asthma medications in the 12 months pre versus the 12 months post-initiation of omalizumab treatment

10. The proportion of patients in whom initiation of omalizumab was compliant with NICE (English and Welsh centres) and SMC (Scottish centres) criteria for omalizumab use
11. The proportion of patients classed by the clinician as 'responders' to omalizumab treatment at 16 weeks
12. Distribution of characteristics of patients who have been prescribed omalizumab in normal clinical practice (age, sex, race, smoking status, height, weight, allergies and co morbidities at baseline)
13. The difference in patient weight at baseline and 12 months post-omalizumab initiation

**Completion date**

01/08/2013

## Eligibility

**Key inclusion criteria**

1. Patient to receive at least one dose of omalizumab for the treatment of severe persistent allergic asthma as part of normal clinical care
2. Patient aged 16 or over at initiation of omalizumab

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Complete patient medical record for the 12 months pre-initiation of omalizumab is not available for review
2. Medical record contains insufficient data to complete the baseline study dataset (for patients recruited to the study after omalizumab initiation)
3. Patient declines to consent to research access to the medical record and/or researcher contact with the GP to obtain a complete study dataset
4. Previous bronchial thermoplasty
5. Previous omalizumab use
6. Current participation in any interventional trial of asthma treatment

**Date of first enrolment**

01/03/2012

**Date of final enrolment**

01/08/2013

## Locations

## **Countries of recruitment**

United Kingdom

England

## **Study participating centre**

**Novartis Pharmaceuticals UK Ltd**

Surrey

United Kingdom

GU16 7SR

## **Sponsor information**

### **Organisation**

Novartis Pharmaceuticals (UK)

### **ROR**

<https://ror.org/039s6n838>

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

Novartis Pharmaceuticals UK Limited

### **Alternative Name(s)**

Novartis UK, NOVARTIS UK LIMITED

### **Funding Body Type**

Private sector organisation

### **Funding Body Subtype**

For-profit companies (industry)

### **Location**

United Kingdom

## **Results and Publications**

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/06/2013		Yes	No