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The impact of omalizumab treatment in UK clinical practice for asthma

Submission date 11/04/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 10/05/2012	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 13/02/2018	**Condition category** Respiratory	[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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)

Secondary outcome measures

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 ang 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 betweeen change in number of exacerbations and change in lung function from basline 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 priactice (age, sex, race, smoking status, height, weight, allergies and co morbidities at baseline)
13. The difference in patient weight at baseline and12 months post-omalizumab initiation

Overall study start date
01/03/2012

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

Age group
Adult

Sex
Both

Target number of participants

100 adults

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
England

United Kingdom

Study participating centre
Novartis Pharmaceuticals UK Ltd
Surrey
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Sponsor information

Organisation
Novartis Pharmaceuticals (UK)

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Sponsor type

Industry

Website
http://www.novartis.co.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	01/06/2013		Yes	No