Aim This multicentre observational study was conducted to confirm the observed retrospective findings prospectively in UK clinical practice.
Methods Retrospective data were collected in the 12 months prior to and prospective data for up to 12 months following omalizumab initiation. The primary endpoint was the change in mean daily OCS dosage (reported previously). Secondary endpoints included changes in mean exacerbation frequency (defined as requiring hospital admission or Accident and Emergency (A&E) attendance and/or a course of OCS (dosage increase of at least 10 mg/day for at least 3 days)), healthcare utilisation and missed days in education or at work.
Results 235 patients were enrolled in the study at end December 2013 in 22 UK centres. Data for interim analysis were examined from patients with 12 months of assessment at database lock (n = 85, females, 54%, mean (±SD) age 44 yr (±13.2), mean (±SD) duration of asthma 26 yr (±14.0)). At the 16 weeks assessment 74/85 (87%) patients were classified as responders to omalizumab treatment. Comparing the 12 month periods prior to and following initiation of omalizumab, mean total exacerbations decreased by 51% from (mean, ±SD) 4.25 ± 2.73 to 2.07 ± 2.01 (mean difference 2.18, $p < 0.001$), while mean exacerbations involving hospital visits decreased by 61% from 1.52 ± 2.00 to 0.59 ± 1.25 (difference 0.93, $p < 0.001$). A&E attendances were reduced from 54 to 19 ($p < 0.01$) and inpatient hospitalisations from 85 to 36 ($p < 0.001$). The percentage of average days absent from work or education due to sickness was more than halved in the 12 months pre and post omalizumab initiation reducing from 19.6% to 7.72% (n = 27, $p < 0.05$).
Conclusions The data prospectively confirms that omalizumab is associated with significant reduction in exacerbations, healthcare utilisation and societal burden in severe allergic asthma patients as was reported in the retrospective study.

S94 A PROSPECTIVE STUDY INVESTIGATING ORAL CORTICOSTEROID (OCS) USE AND QUALITY OF LIFE IN OMALIZUMAB TREATED SEVERE ALLERGIC ASTHMA PATIENTS – RESULTS FROM AN INTERIM ANALYSIS OF THE APEX II STUDY

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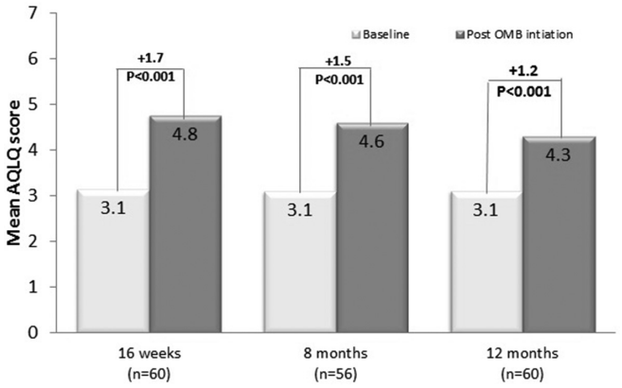
10.1136/thoraxjnl-2014-206260.100

Background A previous retrospective study of UK clinical practice demonstrated that omalizumab reduced OCS burden.
Aim This multi-centre observational study was conducted to confirm the observed retrospective findings prospectively.
Methods Retrospective data were collected in the 12 months prior to omalizumab, while prospective data were collected at 16 weeks, 8 and 12 months following initiation. The primary endpoint was the change in mean daily OCS dose in the 12 months pre and post omalizumab initiation. Secondary endpoints included changes in ACT and AQLQ scores in the 12 months pre and post omalizumab initiation.
Results 235 patients were enrolled by the end December 2013 in 22 UK centres. Data for interim analysis were examined from patients who had 12 months assessment at database lock (n = 85, 54% females, mean (±SD) age 44 yr (±13.2), mean (±SD) duration of asthma 26 yr (±14.0)). At the 16 weeks assessment 74/85 (87%) patients were classified as responders to omalizumab treatment. At 12 months, mean daily OCS dose decreased by 25% (n = 85, $p < 0.001$) from 10.77 mg/day (±7.87) to 8.08 mg/day (±8.39) and 55% (n = 46/84) of patients stopped OCS. 71% (n = 60/85) of patients stopped or reduced OCS by ≥20%. Comparing the 12 months periods prior to and following initiation of omalizumab, the mean ACT score improved from 9.8 (±4.8) to 14.2 (±5.2) (n = 75, $p < 0.001$) and the mean AQLQ score improved from 3.1 (±1.3) to 4.3 (1.46) (n = 60, $p < 0.001$) [Graph 1].



Abstract S94 Graph 1 Mean AQLQ score pre and post omalizumab initiation - ITT group

Conclusions The data prospectively confirms that omalizumab is associated with statistically and clinically significant reduction in OCS and statistically and clinically significant improvement in asthma symptom control and quality of life.

S95 DOUBLE-BLIND MULTI-CENTRE RANDOMISED CONTROLLED TRIAL OF VITAMIN D3 SUPPLEMENTATION IN ADULTS WITH INHALED CORTICOSTEROID-TREATED ASTHMA (VIDIAS)

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10.1136/thoraxjnl-2014-206260.101

Introduction and objectives Asthma exacerbations are commonly precipitated by viral upper respiratory infections (URI). Vitamin D insufficiency associates with susceptibility to URI in patients with asthma. A recent vitamin D trial in adults with asthma reported a trend towards reduced exacerbation risk in the intervention arm as a secondary outcome. Trials of vitamin D in adults with asthma with incidence of exacerbation and URI as primary outcome are lacking. We therefore conducted a multicentre randomised controlled trial of vitamin D_3 supplementation in adults with asthma with co-primary outcomes of severe exacerbation and URI.
Methods Two hundred and fifty adults with inhaled corticosteroid (ICS)-treated asthma were allocated to receive six 2-monthly oral doses of 3 mg vitamin D_3 or placebo over one year. Co-primary outcomes were time to first severe exacerbation and time to first URI. Sub-group analyses were performed to determine whether effects of supplementation were modified by baseline vitamin D status or genotype for thirty-four single nucleotide polymorphisms in eleven vitamin D pathway genes.

Thorax: first published as 10.1136/thoraxjnl-2014-206260.100 on 10 November 2014. Downloaded from http://thorax.bmj.com/ on April 9, 2024 by guest. Protected by copyright.