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). 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].

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.

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 OCS score decreased by 2.18 mg/day (n = 46, p < 0.001) and the mean AQLQ score improved from 23.1 (±1.3) to 24.3 (1.46) (n = 60, p < 0.001) [Graph 1].

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.