healthy controls. Similarly, there was no significant difference in serum VDBP between any of the above groups (p=0.52). VD or VDBP serum levels did not correlate with exacerbations ( $r_s$ =0.08, p=0.28 for VD and  $r_s$ =-0.04, p=0.76 for VDBP), FEV1, or FeNO.

## Abstract P14 Table 1

| Group(n) | Vit<br>Dmcg/l* | vitDBPmg/dl*  | FENOppb†    | FEV1(I)†    | FEV1%†       | Exacerba-<br>tions(n)† |
|----------|----------------|---------------|-------------|-------------|--------------|------------------------|
| H (15)   | 22.59 (14)     | 40.4 (23.42)  | 15.3 (6.4)  | 3.53 (0.56) | 105.1 (29.1) | 0                      |
| MA (15)  | 20.38 (12.6)   | 49.09 (21.91) | 37.6 (24.2) | 3.35 (0.97) | 99.5 (15.8)  | 0.13 (0.52)            |
| SA (10)  | 15.95 (15.5)   | 47.57 (16.73) | 44.1 (39)   | 2.35 (1.14) | 68.5 (24.2)  | 5.9 (5.5)              |
| SACS(10) | 20.35 (41.0)   | 37.41 (19.23) | 65.8(81.4)  | 2.56 (0.92) | 80.0 (8.06)  | 35.9 (43.6)            |
| BA1 (10) | 16.15 (13.9)   | 39.93 (25.58) | 65.7 (55.8) | 1.94 (0.73) | 72.3 (25.1)  | 24.3 (39.7)            |

<sup>\*</sup>median(IQR).

**Conclusion** VD and VDBP level in various asthma groups, did not differ significantly from healthy volunteers in this cohort, and did not correlate with lung function, asthma exacerbations, or exhaled nitric oxide. We conclude that vitamin D axis may not play a significant role in asthma severity or exacerbations although a small effect could not be excluded which would require a larger study for confirmation.

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P15

## CONCERNS ABOUT CORTICOSTEROIDS AMONG PEOPLE WITH ASTHMA: IMPLICATIONS FOR CLINICAL INTERVENTIONS

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**Introduction and Objectives** Despite the effectiveness of inhaled and systemic corticosteroids in controlling and preventing asthma exacerbations, suboptimal rates of adherence to treatment have been well documented. Previous studies have highlighted the importance of patients' beliefs about their medicine in determining their adherence to inhaled corticosteroids. The aim of this study was to examine in-depth people's concerns about inhaled and systemic corticosteroids for asthma and their relation to treatment adherence, and to assess the use of and satisfaction with available sources of information about corticosteroids to inform the development of interventions to support patients.

**Method** Validated questionnaires measuring concerns about steroid inhalers and tablets (Beliefs about Medicine Questionnaire), satisfaction with information (Satisfaction with Information about Medicines Scale) and adherence (Medication Adherence Report Scale) were sent to Asthma UK members or completed online via the Asthma UK website.

**Results** 2659 people returned questionnaires. Respondents reported a range of concerns about steroid medicines. The most prevalent concerns about steroid inhalers were about potential long-term effects (60%) side effects (sore throat or oral thrush (43%); effects on the voice (37%)) and becoming dependent on the inhaler (36%). The most prevalent concerns about steroid tablets were about long-term effects (81%), side effects (concerns about weight gain (66%); weakened bones (65%)) and general worry about taking the tablets

(62%). People had stronger concerns about steroid tablets compared to steroid inhalers (p<0.0001). Concerns about treatment were associated with lower adherence to steroid inhalers (p<0.0001) and steroid tablets (p<0.0001). The most frequent sources of information used by people to address their concerns were reading the patient information leaflet and consulting nurses and doctors. Two-thirds of the sample indicated that they were dissatisfied with the information they had received about steroid treatments.

**Conclusion** People with asthma had a range of concerns about steroid medicines which impacted negatively on adherence. For many, treatment concerns had not been alleviated by the available information sources. Developing and implementing interventions that address patients' concerns about the side effects of corticosteroids may improve adherence to asthma treatment and improve asthma control.

P16

FLUTICASONE PROPIONATE/FORMOTEROL FUMARATE
COMBINATION THERAPY HAS AN EFFICACY AND SAFETY
PROFILE SIMILAR TO THAT OF ITS INDIVIDUAL
COMPONENTS ADMINISTERED CONCURRENTLY: A
RANDOMISED CONTROLLED TRIAL

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Introduction and objectives A new asthma therapy combining fluticasone propionate (FP) and formoterol fumarate (FORM) in a single pressurised metered dose inhaler (FP/FORM) has been developed. The efficacy and safety of FP/FORM (500/20  $\mu g$ ) were compared with its components FP and FORM, administered concurrently (FP +FORM), with FP alone and with FP/FORM (100/10  $\mu g$ ).

**Methods** Adults with moderate—severe reversible asthma were randomised 1:1:1:1 to 8 weeks of treatment with FP/FORM (500/  $20\,\mu g$  or  $100/10\,\mu g$ ), FP+FORM (500  $\mu g$ +24  $\mu g$ ), or FP 500  $\mu g$  alone (all twice daily) in a double-blind, double-dummy, multicentre, parallel-group study. The primary endpoint was change in mean morning pre-dose FEV<sub>1</sub> from baseline to end of treatment for FP/FORM (500/20  $\mu g$ ) and FP+FORM. Results for FP/FORM (500/  $20\,\mu g$ ) and FP+FORM are presented.

Results FP/FORM was as effective as FP+FORM, with an increase in mean morning pre-dose FEV<sub>1</sub> of 0.3451 (n=133) and 0.2841 (n=140), respectively at the end of week 8 (per protocol groups; least squares (LS) mean of the treatment difference: 0.0601; noninferiority 95% CI:-0.059 to 0.180; p<0.001). The co-primary objective of this study supported this finding. The mean change in FEV<sub>1</sub> from pre-morning dose on Day 0-2h post-morning dose at end Week 8 was 0.5181 in the FP/FORM group and 0.5001 in the FP +FORM group (per protocol groups; LS mean of the treatment difference: 0.0181; non-inferiority 95% CI:-0.098 to 0.135; p<0.001). Six patients receiving FP/FORM and 11 patients receiving FP+FORM discontinued due to lack of efficacy (per protocol groups). In both treatment groups, mean asthma symptom scores and sleep disturbance scores were low (intent to treat groups, Day 0: mean asthma symptom scores <1.2; mean sleep disturbance scores <0.7) and improved from Day 0 to end week 8. Salbutamol rescue medication use was comparable (median percentage of study days used: FP/FORM: 23.95%; FP+FORM: 21.05%; Hodges Lehmann difference: 0.06; 95% CI:-4.29 to 4.44; p=0.835). 19.5% of FP/ FORM and 19.9% of FP+FORM patients experienced at least one AE. Most AEs were mild or moderate.

**Conclusion** FP/FORM and FP+FORM had similar efficacy and safety profiles.