receive oral prednisolone or placebo as per COBRA regime, started on oral prednisolone at a dose of 60 mg, rapidly tapered weekly to reach a dose of 10 mg by 6 weeks and subsequently maintained on a low dose of 5 mg till 24 weeks. Primary end point was 50% improvement in BASDAI at week 24. Secondary end points were improvement in ASDAS and BASFI. Analysis was by intention-to-treat. Trial Registration# CTRI/2018/01/011342

Results: This study enrolled 65 patients (62 males) who were randomized to corticosteroid (n=32) or placebo (n=33) with mean $\pm$ SD age 28.5 ± 8.4 years and BASDAI 5.4 ± 1.0 . Primary end point was reached in 12 (37.5%) and 3 (9%) patients treated with steroids and placebo respectively ($p=0.007$). On repeated measures analysis by general linear model, there was a significant difference between the two-groups in BASDAI ($p=0.03$) (Figure-1). Patients in the corticosteroid group had significant improvement in BASDAI, ESR, CRP, ASDAS ESR and ASDAS CRP at 24 weeks (Table-1). Clinically important improvement in ASDAS CRP was achieved by significantly higher number of patients in steroid group (17 (55%) vs 6 (18%), $p=0.002$). Major improvement in ASDAS ESR and ASDAS CRP was also higher in the steroid group (Figure-2). At 24 weeks, patients in the steroid group had significant reduction in IL-6 levels compared to that in placebo group ($p=0.007$, data for 41 patients). Patients in the steroid group had more weight gain and facial puffiness, however no serious adverse events were noted in both the groups.

Figure 1. Change in mean BASDAI

Table 1. Changes in disease indices and inflammatory markers at 24 weeks

Changes in Parameters (24 weeks-baseline)	Placebo	Corticosteroid	P value
ESR, Median (IQR)	0 (-11 to 21)	-13 (-37 to 4)	0.01
CRP mg/L	0 (-8.8 to 13)	-9 (-22.7 to 0)	0.03
Median (IQR)			
BASDAI (mean $\pm$ SD)	-0.51 $\pm$ 1.6	-1.88 $\pm$ 2.5	0.03
BASMI (mean $\pm$ SD)	-0.25 $\pm$ 0.8	-0.56 $\pm$ 0.9	0.23
BASFI (mean $\pm$ SD)	-0.35 $\pm$ 2.3	-1.48 $\pm$ 3.1	0.28
BAS-G (mean $\pm$ SD)	-1.02 $\pm$ 2.7	-1.86 $\pm$ 2.5	0.32
ASDAS-ESR (mean $\pm$ SD)	-0.13 $\pm$ 1.0	-1.11 $\pm$ 1.1	0.001
ASDAS-CRP (mean $\pm$ SD)	-0.24 $\pm$ 1.1	-1.17 $\pm$ 1.3	0.006

Figure 2. Clinically important and Major improvement at 24 weeks

Conclusion: Oral prednisolone given by COBRA regime was associated with significant improvement in disease activity scores in axial SpA at 24 weeks. This extends and supports results from a previous short term study.³ Thus, corticosteroids may be an option for patients not having access to biologics, atleast for the short-term.

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OP0109 CO-MEDICATION WITH A CONVENTIONAL SYNTHETIC DMARD IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS IS ASSOCIATED WITH IMPROVED RETENTION OF TNF INHIBITORS: RESULTS FROM THE EUROSPA COLLABORATION

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Background: Axial spondylarthritis (axSpA) patients treated with a tumour necrosis factor inhibitor (TNFi) may receive a concomitant conventional synthetic disease-modifying anti-rheumatic drug (csDMARD), although the value of combination therapy remains unclear.

Objectives: Describe the proportion and phenotype of patients with axSpA initiating their first TNFi as monotherapy compared to TNFi+csDMARD combination therapy, and to compare the 1-year TNFi retention between the two groups.

Methods: Data from 13 European registries was collected. Two exposure treatment groups were defined: TNFi monotherapy at baseline (=TNFi start date) and TNFi+csDMARD combination therapy. TNFi retention rates were assessed with Kaplan-Meier curves for each country and combined. Hazard ratios (HR, 95% CI) for discontinuing the TNFi were obtained with Cox models: (i) crude; adjusted for (ii) country, and (iii) country, sex, age, calendar year, disease duration and BASDAI. Participating countries were dichotomized into two strata, depending on their 1-year retention rate being above (stratum A) or below (stratum B) the average retention rate across all countries.

Results: 22,196 axSpA patients were included with 34% on TNFi+csDMARD combination therapy. Baseline characteristics are presented in table 1. Overall, the crude TNFi retention rate was marginally longer in the combination therapy group (80% (79-81%)) compared to the monotherapy group (78% (77-79%)) and was primarily driven by differences in stratum B (fig. 1). TNFi retention rates varied significantly across countries (range:-11.0% to +11.3%), with a clear distinction between the 2 strata. The HRs for discontinuation over 1-year (reference=TNFi monotherapy) in the 3 models were: (i) 0.88 (0.82-0.93), (ii) 0.87 (0.82-0.92), (iii) 0.88 (0.82-0.93).

Conclusion: Considerable differences were observed across countries in the use of combination therapy and TNFi retention in axSpA patients. The overall 1-year TNFi retention was higher with csDMARD co-therapy compared to TNFi monotherapy. TNFi monotherapy had a 12-13% higher risk of treatment discontinuation.

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Table 1

Baseline characteristics	All patients (n=22196)	Country stratum A		Country stratum B	
		TNFi mono (n=4940)	csDMARD + TNFi (n=2547)	TNFi mono (n=9693)	csDMARD + TNFi (n=5016)
Age (years), mean (SD)	42.6 (12.5)	43.4 (12.0)	42.8 (12.2)	41.6 (12.7)	43.7 (12.7)
Females, %	41.1	37.7	38.2	42.0	44.2
Disease duration (yrs), mean (SD)	5.7 (8.0)	6.2 (7.7)	6.7 (7.4)	4.9 (8.2)	6.1 (8.2)
Enthesitis, %	50.3	16.7	33.9	57.8	59.7
SJC-28, median (IQR)	0 (0-1)	0 (0-0)	0 (0-2)	0 (0-0)	0 (0-2)
VAS pain (0-100), mean (SD)	60.9 (24.5)	63.3 (26.5)	67.8 (23.3)	60.2 (23.4)	57.2 (24.3)
CRP (mg/L), median (IQR)	8 (3-20)	7.8 (2-20)	18 (6.7-32.6)	6.0 (2.7-15)	8.0 (3-22)
BASDAI (0-10), mean (SD)	5.7 (2.1)	5.7 (2.2)	6.2 (2.1)	5.6 (2.0)	5.4 (2.2)
BASFI (0-10), mean (SD)	4.4 (2.5)	4.4 (2.6)	4.9 (2.5)	4.3 (2.4)	4.2 (2.9)
ASDAS, mean (SD)	3.5 (1.1)	3.7 (1.0)	4.0 (1.0)	3.3 (1.0)	3.3 (1.1)
On Infliximab, %	25.7	21	22	24	36
Baseline csDMARD use, %					
-Methotrexate		0	45	0	63
-Sulfasalazine		0	68	0	33
-Leflunomide		0	8	0	1

Figure 1. Retention rate of TNFi monotherapy vs TNFi and csDMARD comedication, stratified by each country's one-year retention rate being above (stratum A) or below (stratum B) the average one-year retention rate

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OP0110

IS VERY EARLY TREATMENT EFFECTIVE? SIX MONTHS RESULTS OF THE PREVAS STUDY, A PLACEBO-CONTROLLED TRIAL WITH ETANERCEPT IN PATIENTS SUSPECTED OF NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

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Background: Despite the new classification criteria for non-radiographic axial spondyloarthritis (nr-axSpA) patients according to the Assessment of Spondyloarthritis International Society (ASAS), there are limited data on disease progression in nr-axSpA patients.

Objectives: First to assess the improvement in disease activity in patients suspected of nr-axSpA after 16 weeks treatment with Etanercept (ETN) or Placebo (PBO). Second, to assess the changes of active inflammation on MRI of the SI-joints (SIJ) between the ETN and PBO group after 16 and 24 weeks without study medication.

Methods: The PrevAS study is a randomized, double blind, placebo-controlled trial with ETN performed in the VU University medical center (VUmc) (EudraCT number 2009-015515-40), with a screening period from 2009 until 2014. Patients suspected of nr-axSpA were included if they had chronic back pain for ≥ 3 months, were ≥ 18 years, fulfilled the Calin criteria of inflammatory back pain and had to be either HLA-B27 positive with at least ≥ 1 Spondyloarthritis (SpA)-feature (as defined by the European Spondyloarthropathy Study Group (ESSG), or HLA-B27 negative with at least ≥ 2 SpA-features and had a high disease activity score (Bath Ankylosing Spondylitis Disease Activity Index ≥ 4) plus insufficient response to at least two NSAIDs. Excluded were patients who fulfilled the modified New York criteria for ankylosing spondylitis, or in case of previous biological use. Included patients were randomly assigned (1:1) for 16 weeks treatment with ETN (N=40) or PBO (N=40) and followed after the treatment period for 24 weeks. The primary endpoint was the number of patients achieving the ASAS20 response at week 16. MRI was performed at baseline, 16 and 24 weeks and scored using the Spondyloarthritis Research Consortium of Canada (SPARCC) index for number of active inflammatory lesions.

Results: The majority of included patients was female (63.8%). Patient characteristics, like the presence of the HLA-B27 antigen and number of SpA-features