who achieved BASDAI 20/50/70 response gradually increased from week 6 to week 24 or 30 in Naïve group with AS (Figure 1).
Fifty percent of naïve patients with PsA achieved clinical remission. The proportions of both PASI 50 and 75 responses were 50% at Week 22 in Naïve group and were 100% and 50% in Switch group, respectively during post-baseline visits in PS patients.
Throughout this study, treatment-emergent adverse events (TEAE) and treatment-emergent serious adverse events (TESAE) were reported as Table 2. Only 11% of patients experienced infection.

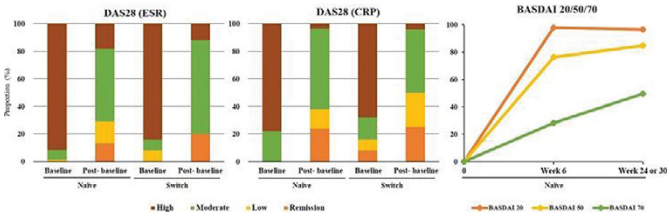
Table 1. Clinical remission in RA and AS

		Naïve		Switch	
		Baseline	Post-baseline	Baseline	Post-baseline
RA	DAS28 (ESR)	0/181 (0.0%)	24/182 (13.1%)	0/25 (0.0%)	5/25 (20.0%)
	DAS28 (CRP)	0/180 (0.0%)	43/179 (24.0%)	2/25 (8.0%)	6/24 (25.0%)
AS	BASDAI	2/292 (0.7%)	199/292 (68.2%)	112/209 (53.6%)	150/210 (71.4%)

Table 2. Summary of safety results

n/N (%)	RA	AS	PsA	PS
TEAE	198/400 (49.5)	183/531 (34.5)	1/3 (33.3)	3/6 (50.0)
TEAE related with CT-P13	73/400 (18.3)	64/531 (12.1)	0/3 (0.0)	2/6 (33.3)
TESAE	52/400 (13.0)	14/531 (2.6)	0/3 (0.0)	1/6 (16.7)
TESAE related with CT-P13	15/400 (3.8)	6/531 (1.1)	0/3 (0.0)	0/6 (0.0)
Infusion-related reactions	28/400 (7.0)	11/531 (2.1)	0/3 (0.0)	0/6 (0.0)

Figure 1. Clinical response of RA and AS



Conclusions: CT-P13 is efficacious and well-tolerated in RA/AS/PsA/PS patients. Efficacy and safety results in patients treated with CT-P13 were clinically consistent to historical data [1,2,3]. Especially, Switch group results showed that CT-P13 provides a useful alternative to other anti-TNFs.
References:
[1] Kobayashi et al (2016).
[2] Hetland et al (2005).
[3] Hetland et al (2010).
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SAT0155 ADALIMUMAB IN COMBINATION WITH NON-METHOTREXATE CONVENTIONAL SYNTHETIC DISEASE MODIFYING RHEUMATIC DRUGS IN A CLINICAL TRIAL SETTING

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Background: Biologics in combination with methotrexate (MTX) are associated with improved outcomes versus monotherapy. However, few data exist regarding the use of non-MTX conventional synthetic disease modifying rheumatic drugs (csDMARDs) with biologics.
Objectives: To assess the effectiveness and safety of adalimumab (ADA) in combination with MTX and non-MTX csDMARDs through 6 months.
Methods: This post hoc analysis used data from the 24-week (wk) placebo-controlled trial of ADA (STAR), assessing safety and efficacy of ADA+csDMARDs in patients (pts) with moderate to severe RA.[1] For those pts receiving 1 csDMARD, pts were subgrouped according to csDMARD. The most frequently used csDMARDs assessed were MTX, sulfasalazine (SSZ), hydroxychloroquine (HCQ), and leflunomide (LEF). Nineteen pts who received parenteral gold in combination with ADA were excluded from this analysis. Baseline demographics and disease characteristics were summarized across csDMARD groups. 20/50/70% improvement in American College of Rheumatology (ACR) response criteria were assessed for each subgroup. Other clinical and functional endpoints were assessed using ANCOVA within subgroups as the least square (LS) means of the mean change from baseline to wk 24. Adverse events (AEs) were monitored throughout.
Results: Of the 290 pts randomized to receive ADA, 237 (82%) received ≥1 csDMARD [174 (60%) and 63 (22%) received ADA in combination with 1 and ≥2 csDMARDs, respectively]. Of the 63 pts who received ≥2 csDMARDs in combination with ADA, 55 (87%) received concomitant MTX therapy. Similarly, most of the pts receiving ADA in combination with a single csDMARD received MTX [114 (66%)], while 60 pts received ADA in combination with a single non-MTX csDMARD. Pts receiving non-MTX csDMARDs were slightly younger, on average, than those receiving MTX (mean age: 51.4 vs 56.4 years), but demonstrated slightly higher mean HAQ-DI (1.37 vs 1.26) and CRP (2.4 vs 1.3) at baseline. Following 6 months of combination therapy, pts receiving ADA+MTX experienced numerically better clinical and functional outcomes to pts receiving ADA+non-MTX csDMARDs (Table). The lower response in the non-MTX DMARD group appeared to be driven by pts receiving LEF, who tended to experience lower levels of response in combination with ADA. Overall, frequencies of AEs were similar between combination therapy with MTX and non-MTX csDMARDs (~90% in both groups). Serious AEs were observed in 10% of pts receiving non-MTX csDMARDs and 5% of pts receiving MTX. A total of 42% in the non-MTX csDMARD and 60% in the MTX group experienced infections during the course of the study. There were 3 serious infections, all occurring in the MTX group.

Table. Week 24 Clinical and Functional Outcomes Among Patients Receiving Adalimumab in Combination With a Single csDMARD

		ADA+non-MTX csDMARD n=60			
Variable	ADA+MTX n=114	Pooled n=60	LEF n=25	SSZ n=12	HCQ n=23
ACR20	69 (61)	27 (45)	8 (32)	7 (58)	12 (52)
ACR 50	40 (35)	14 (23)	3 (12)	4 (33)	7 (30)
ACR70	22 (19)	7 (12)	0 (0)	3 (25)	4 (17)
DAS28(CRP)	-1.912[a]	-1.923[b]	-1.516[c]	-1.979[d]	-2.206[e]
SDAI	-22.60[a]	-22.21[b]	-18.41[c]	-23.80[d]	-24.61[e]
CDAI	-21.90[f]	-20.95[g]	-18.05[c]	-23.79[d]	-22.02[h]
HAQ-DI	-0.509[f]	-0.435[i]	-0.251[e]	-0.595[d]	-0.524[h]

Discrete variables are summarized as n (%).
All continuous variables are within group LS means in mean change from baseline to week 24 using ANCOVA, with csDMARD subgroup as a factor and baseline value as covariate, with the exception of the pooled group, which is mean change from baseline.
[a]n=105; [b]n=52; [c]n=20; [d]n=11; [e]n=21 ; [f]n=106; [g]n=53; [h]n=22; [i]n=54.
csDMARDs, conventional synthetic disease-modifying antirheumatic drugs; ADA, adalimumab; MTX, methotrexate; LEF, leflunomide; SSZ, sulfasalazine; HCQ, hydroxychloroquine; ACR, American College of Rheumatology; DAS28(CRP), 28-joint disease activity score based on C-reactive protein; SDAI, simplified disease activity index; CDAI, composite disease activity index; HAQ-DI, health assessment questionnaire disability index.

Conclusions: MTX administered in combination with biologics, like ADA, leads to superior outcomes vs monotherapy. For pts who can't tolerate MTX, non-MTX csDMARDs, specifically HCQ and SSZ but not LEF, may be good alternatives, as outcomes were largely comparable with those of pts receiving MTX when combined with ADA. The limited sample size examined in this analysis should be confirmed in a larger pt population.
References:
[1] Furst DE, et al. J Rheum 2003;30(12):2563–71.
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SAT0156 EXPOSITION TO BIOLOGICAL THERAPY DURING PREGNANCY: A SINGLE-CENTRE STUDY OF PREGNANCY OUTCOME IN MOTHERS WITH RHEUMATIC DISEASES

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Background: Biologic DMARDs fall within the FDA category B or C. However many case series and registry data are available about women exposed during pregnancy.
Objectives: to extend information on this topic by the contribution of a tertiary single centre case series
Methods: Data were collected from a single-centre cohort of outpatients followed between 2006 and 2016. Women with rheumatic diseases (RD) exposed to biological (BE) agent during pregnancy or in the 3 months before conception were included. Outcomes in the BE group were compared with an age-matched group of pregnant women with RD non-exposed to biological agent (NE). Demographic and clinical data,obstetric outcome and neonatal complications were recorded.
Results: 34 pregnancies in 28 patients were included: 14 Rheumatoid Arthritis (RA), 6 ankylosing spondylitis (AS), 2 Psoriatic arthritis (PsA), 4 Undifferentiated spondyloarthritis (uSpA), 1 Dermatomyositis (DM), 1 Adult Onset Still's disease