Although in diffuse cutaneous subgroup, the sensitivity was >96 for both criteria, in limited cutaneous subgroup, the sensitivity was preserved for ACR/EULAR(2013) while apparently decreased for ACR(1980) criteria (<70). The sensitivity for both of the two sets were lowest in the sclerodermic group. In SSC patients with limited or no skin involvement, non-skin manifestations, NVC findings and specific serology should be carefully sought. Some of these patients could not be classified by the current criteria.

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Spondyloarthritis - treatment

THU0370

CLUSTER-RANDOMIZED PRAGMATIC CLINICAL TRIAL EVALUATING THE POTENTIAL BENEFIT OF A TIGHT-CONTROL AND TREAT-TO-TARGET STRATEGY IN AXIAL SPONDYLOARTHRITIS: THE RESULTS OF THE TICOSPA TRIAL.

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Background: Current recommendations for axial spondyloarthritis (axSpA) management include tight control and treat-to-target (TC) strategies, but no study has evaluated its potential benefit.

Objectives: To evaluate the benefit of TC strategies in comparison to usual care (UC) in patients with axSpA.

Methods: *Study design:* Pragmatic, prospective, cluster-randomized controlled (2 arms), one-year trial (NCT03043846). *Centers:* 18 axSpA expert centers randomly allocated (1:1) to the treatment arm: TC vs. UC. *Patients:* axSpA diagnosis and ASAS criteria, non-optimally treated with NSAIDs, bDMARD-naïve, and ASDAS > 2.1 at inclusion. *Study treatment:* a) TC arm: the strategy was pre-specified by the scientific committee based on current axSpA recommendations and aiming at a target (ASDAS <2.1); visits every 4w; b) UC arm: treatment decisions were at the rheumatologist's discretion with visits every 12w. *Outcomes:* the % of patients with a significant (>30%) improvement in the ASDAS-HI score over one-year follow-up was the main outcome. Other outcomes (disease activity, quality of life, treatment, ...) over follow-up were evaluated (Table 1). The number/type of adverse events were collected. *Statistical analysis:* this was an intention-to-treat analysis. To take into account the cluster-randomization design, for all outcomes, two models were performed: first a two-level mixed model with 2 random effects was used to estimate the % of responders/the change of the outcome over follow-up (i.e. mod1); in a second step, the imbalanced variables observed at baseline were included in the model (i.e.mod2). Cost-effectiveness was assessed by estimating the (baseline- and cluster-adjusted) incremental cost per quality-adjusted life-year (QALY) gained for TC vs. UC.

	Estimated outcomes at week 48		Cluster-adjusted (mod1)	Cluster and imbalance-adjusted (mod2)
	TC	UC		
ASDAS LDA*	76.5%	59.5%	<0.01	0.03
ASDAS ID	25.9%	18.7%	-	-
ASDAS CII	61.2%	46.0%	<0.01	0.02
ASDAS MI	16.5%	14.9%	-	-
ASAS40	52.3%	34.7%	<0.01	0.01
ASAS20	94.9%	85.9%	<0.01	0.03
BASDAI 50	79.0%	43.8%	0.01	0.03
Physician Global (0-10)	2.0 (0.2)	1.8 (0.2)	-	-
CRP (mg/L)	3.9 (1.4)	3.5 (1.5)	-	-
BASG (0-10)	2.6 (0.5)	3.4 (0.5)	0.09	-
BASFI (0-10)	1.7 (0.5)	2.4 (0.5)	-	-
ASAS HI SMD	47.3%	36.1%	-	-
EQ5D	0.7 (0.1)	0.8 (0.1)	0.02	-
ASAS-NSAID score	1.5 (2.2)	- 4.9 (2.9)	-	-

Results: 160 patients were included (80 in TC and 80 in UC). Mean age was 37.9(11.0) years with a disease duration of 3.7(6.2) years, 51.2% were males. A radiographic damage of the SI-joints, a (ever) positive MRI sacroiliitis and HLA-B27+ were seen in 46.9%, 81.9% and 75.0% patients respectively. Mean ASDAS at inclusion was 3.0 (0.7) and mean ASASHI was 8.6 (3.7). 72 patients per group attended the one-year visit. Although 47.3% vs. 36.1% patients in the TC and UC arms achieved a significant improvement in ASASHI at the one-year visit, the difference was not statistically significant, with either model. Across all other

outcomes a trend was observed in favor of the TC arm (Table 1). The number of bDMARDs was significantly higher in TC arm (56.2% vs. 27.2%). The number of infections was comparable in both groups (15 vs. 16 in the TC and UC, respectively), with only 2 severe infections occurring in the UC arm. From a societal perspective, TC resulted in an additional 0.04 QALY and saved €265 when compared to UC and a 67% probability of being cost-effective at a cost-effectiveness threshold of €20,000 per QALY.

Conclusion: In this setting of SpA expert centers, UC resulted in a good outcome in a substantial number of patients but the TC was not superior for the primary outcome despite a greater number of bDMARDs prescription. Nevertheless, a general trend in favor of the tight control was observed, with a comparable safety profile and was found to be favorable from a societal health economic perspective.

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THU0371

HIGH INTENSITY EXERCISE HAS COMPARABLE 3-MONTH EFFECTIVENESS TO TNF-INHIBITORS ON DISEASE ACTIVITY IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS. POST-HOC ANALYSES OF DATA FROM (THE ESPA TRIAL.)

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Background: We have previously reported that a supervised 12-week high intensity cardiorespiratory and strengthening exercise programme reduced disease activity in patients with axial spondyloarthritis (axSpA), in an assessor blinded randomized controlled trial (ESPA)(1). There were no reports of disease flare, and the programme was deemed safe. It is of interest to compare the treatment response of the programme vs. the response to treatment with a biologic immune-modulating TNFalpha-inhibitor (TNFi).

Objectives: To compare 3-month change in disease activity following an exercise programme vs. treatment with a TNFi, in patients with axSpA.

Methods: Post-hoc comparison between participants in the intervention group in the ESPA and patients from NOR-DMARD, a longitudinal observational study, who commenced treatment with a TNFi (2). The inclusion criteria of ESPA were a diagnosis of axSpA, age 18-70 years and baseline BASDAI >3.5. Patients fulfilling these criteria were selected from NOR-DMARD. Data was collected at baseline and 3 months. The primary outcome was defined as ASDAS, and BASDAI scores, and secondary outcomes were BASDAI sub-scores and C-reactive protein (CRP). Baseline values were compared in bivariate analyses. Responses at 3 months were compared between the groups using ANCOVA models adjusted for age, gender and baseline values. The standardised mean difference in 3-month response between the exercise and TNFi groups was estimated by dividing the difference in change at 3-months by the standard deviation (SD) of change.

Results: Fifty patients were randomised to the exercise intervention in the ESPA study, mean age (SD) 45.2 (0.6), 25 males (50%). 344 patients in the NOR-DMARD study were eligible for the current analyses, mean age (SD) 39.6 (1.5), 150 males (43.6 %). Baseline demographics and estimated marginal means for disease activity at - months are presented in table 1. The standard mean differences are presented in Figure 1. There were no significant differences in change in disease activity at 3-months between patients participating in ESPA and patients starting a TNFi.