assessed. Missing data were recorded as non-response and Fisher's exact test was used to compare the proportion of responders between groups at Wk 16. Only pooled data for pts receiving the licensed dose of SEC (150 mg) are shown.

Results: Overall 739 patients were included, with 427 and 312 in the SEC 150 mg and PBO groups, respectively. Of those, 37% and 36% of the SEC and PBO groups, respectively, were classified as <2 yrs since first AS diagnosis (Overall: 37%). The mean time since AS diagnosis was similar for the PBO and SEC treatment groups in both the <2 yrs (approx. 0.80 yrs) and the ≥2 yrs subgroups (approx.11 yrs). The least squares mean (LSM) changes in PCS from BL to Wk 16 were increased with SEC 150 mg compared with PBO, in both <2 yrs (PBO: 2.11; 150 mg: 6.44, p<0.0001) and ≥2 yrs since diagnosis (PBO: 3.03; 150 mg: 5.82, p<0.0001) groups. Significant increases were also reported in LSM changes in MCS scores from BL to Wk 16 with SEC 150 mg in patients <2 yrs since diagnosis (PBO: 2.10; 150 mg: 5.53, p<0.01), but not in the ≥2 yrs group. Analysis of individual SF-36 domain scores showed improvements with SEC vs PBO in the overall population and in both time since diagnosis subgroups, except Role-Emotional and Mental Health in the ≥2 yrs group (Figure). At Wk 16, the proportions of PCS responders were significantly higher with SEC 150 mg vs PBO, regardless of time since diagnosis (<2 yrs: PBO = 50.0%, SEC = 73.6%, p<0.01; ≥2 yrs: PBO = 45.0%, SEC = 69.8%, p<0.0001). MCS responses were not significantly different with SEC vs PBO in either subgroup. Overall, improvements in SF-36 scores and clinically meaningful MCID responses with SEC were more prominent in the <2 yrs since diagnosis compared with the ≥2 yrs group. Improvements in PCS, MCS, individual SF-36 domains and overall MCID responses were sustained to Wk 52 with SEC 150 mg.

Conclusion: Treatment with SEC 150 mg resulted in significant, clinically meaningful, and sustained improvements in HRQoL. Although reported irrespective of time since AS diagnosis, improvements were more prominent in earlier diagnosed pts.

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Figure: SF-36 individual domain scores in the overall study population and time since diagnosis subgroups at Weeks 16 and 52. The least squares mean changes from baseline in all domains were significantly improved with SEC 150 mg versus PBO, except for Role Emotional and Mental Health in the ≥ 2 years subgroup at Week 16.

FRI0389

EFFECTIVENESS OF BIOLOGIC THERAPY ON DISEASE ACTIVITY IN ANKYLOSING SPONDYLITIS: A BIOBADASER III OBSERVATIONAL STUDY

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Background: The advent of biologic therapy (BT) in ankylosing spondylitis (AS) has substantially benefited patients with inadequate response to conventional therapy. However, it is known patients with inadequate response to a 1st BT have worse response to 2nd and further lines.

Objectives: To analyze the effectiveness of BT in biologic-naïve and biologic-experienced real-world AS patients, measuring response through change in activity indexes (ASDAS-CRP and BASDAI) and percentage of low activity and inactive disease at 12 months.

Methods: Data were obtained from BIOBADASER III, an ongoing observational longitudinal multicenter cohort of patients with rheumatic diseases treated with BT or targeted synthetic DMARDs. Patients were divided into 2 groups, according to their state before entering the study: BT-naïve (BTn) receiving their 1st BT, and BT-experienced (BTe) receiving their 2nd or further BT; regardless of the specific drug they received. Disease activity indexes (DAI) were collected at baseline and after 12 months of BT; mean and SD was calculated for each group and interpreted according to ASDAS disease activity states and, since not established, analogous categories previously used for BASDAI (<2 inactive, ≥2 <4 low, ≥4 <6 high, ≥6 very high)¹. Clinical response was assessed by ASDAS improvement cut-offs (≥1.1 clinically important improvement (CII), ≥2 major improvement (MI) and BASDAI CII (≥1.1)², BASDAI change (Δ) ≥2 or BASDAI50.

Results: 846 patients, (29.3% women, mean age 47.6 years) were included, 422 BTn and 424 BTe. Mean DAI results (table 1): at baseline, AS had high disease activity by BASDAI (>4) and ASDAS (>2.1 to <3.5). At 12 months, disease activity was low on both groups (BASDAI<4, ASDAS >1.3 to <2.1), reaching BASDAI CII; ΔBASDAI≥2 was only achieved in BTn. No group reached BASDAI50. ASDAS CII was reached in all groups, but MI was not seen. Percentage of patients achieving low disease activity and inactive disease are summarized at table 2, being overall higher for the BTn compared to the BTe group.

Table 1. Mean disease activity indexes evolution

Activity index	Biologic-naïve (BTn)			Biologic-experienced (BTe)		
	Baseline (SD)	12 months (SD)	Δ	Baseline (SD)	12 months (SD)	Δ
BASDAI	5.5 (2.0) n=422	3.2 (1.0) n=287	2.3	5.6 (2.3) n=424	3.9 (2.3) n=244	1.7
ASDAS-PCR	3.2 (1.4) n=120	1.7 (1.0) n=64	1.5	3.4 (1.5) n=95	2.0 (0.9) n=50	1.4

Table 2. Percentage of low disease activity and inactive disease by BASDAI and ASDAS

Disease activity states	n,% achieved at 12 months on BTn	n,% achieved at 12 months on BTe
BASDAI low activity	120, 41.8%	72, 29.5%
BASDAI inactive disease	73, 25.4%	58, 23.8%
ASDAS low activity	21, 32.8%	11, 22%
ASDAS inactive disease	23, 35.9%	15, 30%

Conclusion: The mean disease activity on patients starting biologic therapy is high. A clinically important improvement is met after 12 months of therapy, irrespectively of the index used or the prior use of biologics. The delta in DAI is bigger in the biologic-naïve group who receive the 1st BT. The biologic-naïve group also reaches a higher percentage of low disease activity and inactive disease. Further analysis is needed to see if these tendencies remain after separating the groups per type of biologic drug.

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FRI0390 DRUG THERAPY OF ANKYLOSING SPONDYLITIS (AS) DURING PREGNANCY IN REAL CLINICAL PRACTICE

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Background: The emergence of new drugs for the treatment of AS and improvement of life quality of patients led to an increase in the number of pregnancies and births in women with AS. However, the prescription of medication during pregnancy is still a difficult decision for both doctors and patients, and the unreasonable abolition of therapy can lead to increased activity of the AS.

Objectives: was described the frequency of use of various groups of drugs before and during pregnancy, determine the relationship between the abolition or change in the mode of taking nonsteroidal anti-inflammatory drugs (NSAIDs) and the dynamics of back pain.

Methods: the survey involved 86 women with AS, having pregnancies that ended in childbirth, not earlier than 2016. The average age is 34.0 ± 5.8 years and the average duration of the AS is 120 ± 73.5 months. The median term of delivery is 39 [38; 40] weeks, the weight of newborns is 3241.1 ± 484.6 g. During pregnancy, 58 (67.4%) women noted deterioration of health. Among them: increased back pain in the first trimester was 66.7%, in II – 84.6%, in III – 72.2%.

Results: Before pregnancy, NSAIDs were taken by more women (63.4%) as compared to taking in a month of conception (37.2%) and taking during gestation (in trimesters – 25.6%; 34.8%; 9.3%, respectively), $p < 0.05$ in both cases. "On demand", NSAIDs were taken before pregnancy by 41.8% of women, at conception – 37.5%, in trimesters – 50%, 40% and 25%, respectively. There was a tendency for more frequent increase of back pain during pregnancy in women who abolished NSAIDs in the month of conception, or switched to "on demand" (65%), compared with taking NSAIDs daily (50%). Patients who took NSAIDs "on demand" in the first trimester (group 1), more often noted deterioration of health in the second trimester – 34.6%, compared with patients constantly taking NSAIDs (group 2) – 18.2%. In addition, patients in group 1, as well as women who didn't take NSAIDs in the first trimester, more often complained of back pain (54.6% and 53.1%) during gestation compared with patients in group 2 (36.4%). Group 1 patients in the second trimester noted increased back pain during pregnancy in 83.3%, whereas group 2 patients – in 58.3% ($p < 0.01$). Glucocorticoids were taken more often during pregnancy (16.3%; 20.9%; and 22.1% – in trimesters) than before (7%) and at conception (9.3%), $p < 0.01$ in both cases. Sulfasalazine before pregnancy was taken by 16% of women, at conception – 8%, during pregnancy – 3.5% ($p < 0.01$ in both cases). Before pregnancy, only 12.8% of women received biological therapy; at the time of conception (adalimumab, etanercept) – 6.9%, in I and II trimesters – by 2.3% ($p < 0.01$).

Conclusion: During pregnancy and the month of conception, the number of women receiving NSAIDs, sulfasalazine, biological therapy, decreases compared to the period before pregnancy. Glucocorticoids in preparation for pregnancy and gestation are prescribed more often than before pregnancy. Withdrawal of NSAIDs or switch to mode "on demand" in the first trimester is associated with an increase in the frequency of back pain during pregnancy, but due to discrepant data on the safety of continuous use of NSAIDs in the first trimester, correction of therapy with the prescription of low-risk drugs is necessary.

Disclosure of Interests: None declared

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FRI0391

NETAKIMAB IMPROVES PATIENT-RELATED OUTCOMES IN PATIENTS WITH RADIOLOGICAL AXIAL SPONDYLOARTHRITIS: RESULTS FROM RANDOMISED PHASE 3 TRIAL (ASTERA)

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Background: chronic pain, stiffness, fatigue and limited spinal mobility significantly affect quality of life (QoL) in patients (pts) with axial spondyloarthritis (axSpA). There is increasing evidence that IL-17 blockade is highly effective in this pts' population and show benefits in terms of multiple patient-reported outcomes (PROs) in both non-radiological (nr) and radiological (r) axSpA.

Objectives: To evaluate early effects of netakimab (NTK) on PROs in pts with active r-axSpA, based on data of 16-week observation from ongoing phase 3 ASTERA study (NCT03447704).

Methods: ASTERA is a phase 3 international double-blind placebo(PBO)-controlled clinical study. After completion of screening 228 eligible adult pts with r-axSpA (mNew York criteria, 1984), which remained active (BASDAI ≥ 4.0) despite the standard non-steroidal anti-inflammatory drugs (NSAIDs), were randomly assigned (1:1) to receive 120 mg NTK or placebo (PBO) at Week (Wk) 0, 1, 2 and then q2wk through Wk 16. After Wk 16 all patients will continue/be switched to receive NTK up to week 52. PROs were total back pain (10-item numerical range scale), BASDAI, BASFI. Work productivity and QoL were also assessed by Work Productivity and Activity Impairment (WPAI) and 36-item Short Form Health Survey (SF-36), respectively.

Results: Baseline characteristics were similar between treatment arms. The mean age at baseline was 39.14±9.99 years, 75.88% of patients were male and the mean symptoms duration was 4.3±4.48 years. All patients had active (mean BASDAI: 6.21±1.55) r-axSpA, 76.8% of patients were naïve to any biological treatment. Mean total back pain score at baseline was 6.7±1.6 in NTK group and 6.8±1.5 in PBO arm. At Wk1 the difference in total back pain score between study arms became statistically significant (Figure 1). At Wk 16 use of NTK was associated with statistically significant improvements from baseline in BASDAI (-2.8 vs 0.2, $p < 0.0001$), BASFI (-0.9 vs 0.9, $p < 0.0001$) and physical component of SF36 (6.3 vs. -2.6, $p < 0.0001$) (Figure 2). WPAI response in NTK arm was significantly better at Wk 16, as compared with PBO (Table 1).

Conclusion: NTK in treatment of patients with r-axSpA showed rapid improvement in PRO, WP and QoL and was accompanied with improvement in physical function and disease activity.

Table 1. Change in WPAI at week 16 (medians; upper and lower quartiles)

Parameter	NTK (n=114)		PBO (n=114)	
	Baseline	Change from baseline to Wk16	Baseline	Change from baseline to Wk16
% work time missed due to health	0 [0; 18.4]	0 [-11.1; 0]	0 [0; 15.8]	0 [0; 29.9]
% impairment while working due to health	50 [30; 70]	-80 [-40; 0]	50 [40; 70]	10 [-10; 20]
% overall work impairment due to health	55.1 [40; 84]	-15.6 [-40; 0]	60 [50; 75]	1.2 [-10.3; 20]
% activity impairment due to health	60 [40; 80]	-20 [-40; -10]	60 [50; 70]	0 [-10; 20]

Figure 1. Total back pain score within 16 weeks of ASTERA study (means) (* $P < 0.05$ for the comparison with placebo).