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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.

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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).