activity, HAQ-DI, and pain as early as Week 2 (first post-baseline assessment), and improvements in fatigue by M3. Responses were maintained or improved through M3 (monotherapy) or M6 (with background csDMARDs).

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THU0187 DO WE TODAY ALTERNATIVE THERAPIES RHEUMATOID ARTHRITIS TWO OR MORE DISEASE-MODIFYING DRUGS? THE STORY OF HOW A SIMPLE DRUG PENTOXIFYLLINE MAY ENHANCE THE ACTION OF METHOTREXATE IN RHEUMATOID ARTHRITIS

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Background: The treatment of patients with RA (rheumatoid arthritis) is a complicated task, because the achievement of remission and low level of activity often requires administration of 2–3 disease-modifying drugs. In such conditions we often face with the rise of treatment costs and with the increase of therapy side effects. That is why relevant is the search of the drugs increasing the effect of the "gold standard" of RA – therapy - methotrexate, and also frequently used sulphasalazine and leflunomid. Treatment of prior to "Treat to target" is difficult enough, forcing researchers around the world to look for the ways to improve the effectiveness of RA treatment.

Objectives: To explore the possibilities of reducing RA activity on the disease activity score DAS28 CRP by adding pentoxifylline to the methotrexate, sulfasalazine and leflunomide treatment.

Methods: This study included women (n=131) with RA longer than 1 year in duration, having a seropositive rheumatoid factor, and DAS28 CRP activity score of 3.2–5.1. Middle aged – 46.44±3.24 years old. All patients received a 15.50±2.50 mg oral dose of methotrexate per week, 2000±500 mg oral dose of sulfasalazine per day, 20±5 mg oral dose of leflunomide per day. Patients were divided into two groups - those who only had disease-modifying drugs (DMARDs) (n=80) and those who were treated with an oral dose of methotrexate and 1200 mg of pentoxifylline per day (n=51).

Results: The baseline for both groups of RA patients did not differ significantly in terms of the level on the DAS28 CRP (p=0.812). On 14th day of the group who were taking pentoxifylline, the DAS28 CRP disease activity score was significantly lower by 12.5% ($p<0.001$). After 28 days, the users had a DAS28 CRP disease activity score index difference. The difference between two groups is statistically significant. In the group that were treated with pentoxifylline in addition to DMARDs (p=0.001) the index was found to be 8.3% lower. For 28 days, the methotrexate group's disease activity according to the DAS28 CRP activity score significantly decreased by 14.3% from the baseline ($p<0.001$). For 28 days, the pentoxifylline + DMARDs group also achieved a statistically significant reduction in the index according to the DAS28 CRP activity score by 20.5% ($p<0.001$)

The disease activity index for the two groups for 14 and 28 days is shown in the table.

The DAS28 CRP Index in the two groups of RA patients

Groups of patients Observation time	Group DMARDs (n=80)	Group DMARDs +) Pentoxifylline (n=51)	Statistical significant differences between the two groups
Baseline	3.11±0.05	3.13±0.05	p=0.812
For 14 days	3.06±0.05	2.69±0.06	p<0.001
For 28 days	2.71±0.04	2.48±0.06	p=0.001

Conclusions: Thus, converting the monotherapy DMARDs to pentoxifylline will significantly reduce the activity of RA, while avoiding many of the adverse effects of the other combination therapies. This data requires further long-term research.

Disclosure of Interest: None declared

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THU0188 EFFICACY AND SAFETY OF TOFACITINIB IN PATIENTS WITH RHEUMATOID ARTHRITIS WHO DID NOT RESPOND TO SYNTHETIC AND BIOLOGICAL DMARDS IN CLINICAL PRACTICE

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Background: Tofacitinib (TOFA) is so far the only representative of a new class of Jak-kinase inhibitors in rheumatology. Despite extensive data on TOFA obtained from 3rd phase studies, for use in clinical practice, the information is limited.

Objectives: To study the efficacy and safety of TOFA in RA in clinical practice.

Methods: We represent the combined data from two parallel IV Phase open-label observational clinical trials, modelling clinical practice, conducted by very similar protocols in 11 rheumatology centers in Russia. Inclusion criteria were active RA, methotrexate (MTX) failure, and/or other synthetic or biologic DMARDs failure. In total, 142 pts (26 males, 116 females, age 51,5±12,2 years, disease duration 88,6±78,1 months, 86,6% RF(+), 76,6% ACPA(+), 81,7% with erosive disease, DAS28-ESR 5,89±1,03, SDAI 35,7±13,4, HAQ 1,59±0,64) were included. 32 (22,5%) pts had biologics in history. TOFA used in the dose of 5 mg BID for 6 months, with possibility to increase to 10 mg BID (carried out in 27 pts after 11,3±2,7 weeks). 115 (81%) pts received TOFA in combination with MTX (18±4,5 mg per week), 18 with leflunomide or sulfasalazine, 9 pts used TOFA in monotherapy.

Results: 129 (90,8%) pts successfully completed the six-month period of treatment. TOFA was withdrawn due to lack of response in 6 cases, adverse events (AEs) in 4 (pneumonia, arterial hypertension, skin vasculitis, mouth ulcers), withdrawal of informed consent – 2, protocol violation – 1. At month 3 SDAI score decreased to 14,6±10,9 ($p<0,01$), 55 (42,6%) pts achieved SDAI LDA and 22 (17,1%) SDAI remission; HAQ decreased to 0,95±0,61, HAQ≤0,5 observed in 36 (27,9%) pts. After 6 months, SDAI and HAQ scores decreased to 10,5±8,6 and 0,83±0,64 resp. ($p<0,01$); 81 (62,8%) pts achieved SDAI LDA and 29 (22,5%) SDAI remission; HAQ≤0,5 observed in 48 (37,2%) pts. Results of treatment in patients with and without biological DMARDs in history were similar. Pts who needed dose escalation of TOFA had worse results at month 3 compared to others (SDAI 21±10,2 and to 13,2±10,7 resp., p=0,02), but after increase of the dose to 10 mg BID at month 6 they showed a slightly better result (SDAI 9,5±7,1 and to 10,7±8,9 resp., p=0,54). Only 2 serious AEs (pneumonia and skin vasculitis) observed. We didn't see any case of Herpes zoster in our group.

Conclusions: TOFA was effective in patients with severe RA who did not respond to both synthetic and biological DMARDs (achievement of SDAI LDA in 42,6% of pts at month 3 and in 62,8% at month 6). Dose escalation to 10 mg BID can be useful in ¼ of patients who do not respond to standard dose of TOFA. TOFA has shown a good safety profile.

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THU0189 SAFETY OF FOUR TREATMENT REGIMENS IN EARLY RHEUMATOID ARTHRITIS

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Objectives: To compare safety data in patients (pts) with early (<2 years duration) RA who were randomised to receive 4 different regimens of treatment.

Methods: One hundred forty-one pts with RA of less than 2 years duration (122 women, mean age 51 years, mean disease duration 24 weeks, mean DAS 28 5,9; 64% RF-positive,59% ACCP-positive) were randomly allocated to receive one of the following treatment regimens: methotrexate (MTX, up to 20 mg/week,