FRI0050 PATIENTS WITH RHEUMATOID ARTHRITIS ON METHOTREXATE. CASES OF APLASTIC ANAEMIA. FOLLOW UP OF FOURTEEN YEARS

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Background Methotrexate has been recognised as one of the main therapeutic agents used in rheumatoid arthritis (RA). However some of the adverse effects of low-dose methotrexate therapy and in particular pancytopenia have caused major concern.

Objectives The aim was to describe our experience of long-term follow up of patients with RA treated with low-dose methotrexate, in particular in reference to the appearance of pancytopenia.

Methods During the last 14 years 528 RA patients were treated with methotrexate 7.5–15 mg/week by the Rheumatology Department. These patients were followed up by the Rheumatology Department and they had a complete laboratory evaluation and clinical examination in regular intervals.

Results In 528 RA patients treated with low-dose methotrexate therapy over a period of 14 years 4 cases of aplastic anaemia were diagnosed (0.76%). In these patients the white cell count, platelet count, haemoglobin and haematocrit values decreased. In all 4 cases liver function tests were slightly elevated. Folinic calcium was administered and white cell and platelet counts improved, while haematocrit remained stable. The increase in white cell count after the administration of folinic calcium was satisfactory and the addition of growth factors to aid haemopoiesis was not considered necessary. In a female patient a very marked decrease in white cell count was observed and the patient died from sepsis, despite the administration of antibiotics.

Conclusion Low-dose methotrexate therapy in long term follow-up appears to be a safe and effective form of therapy for RA patients. Therapy appears to be well tolerated by the patients. Pancytopenia appears to be one of the most significant and dangerous complications of this form of therapy, being observed even in the absence of other recognised risk factors. Pancytopenia may occur abruptly in patients with RA on low-dose methotrexate therapy. Regular laboratory investigations are essential for the early detection of this complication. The administration of supplement folate in patients with RA on low-dose methotrexate therapy may reduce the incidence of pancytopenia.

FRI0051 DECREASE OF DISEASE ACTIVITY AND DISABILITY AND IMPROVEMENT OF QUALITY OF LIFE IN PATIENTS WITH REFRACTORY LONG-STANDING RHEUMATOID ARTHRITIS TREATED WITH MONOCLONAL ANTI-TUMOUR NECROSIS FACTOR-ALPHA ANTIBODY

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Background Anti-tumour necrosis factor-alpha; (TNF-alpha) antibody has been recently introduced for the treatment of Rheumatoid Arthritis (RA).

Objectives To evaluate the efficacy of anti-tumour necrosis factor-alpha (TNF-alpha) antibody associated with low-dose methotrexate (MTX) on disease activity, disability and quality of life in a group of RA patients non responder to traditional DMARDs.

Methods Forty-five non responder patients (42 F, 3 M; age 52 ± 11.7) with long-standing refractory active (DAS28 >4) rheumatoid arthritis (disease duration 15.5 ± 8.8 years) were included in an open study. Before entry most of the patients were on a combination DMARDs regimen. Patients were treated with slow i.v. infusions (at day 0, 15, 45 and then every 45 days) with monoclonal anti-TNF-alpha antibody (Infliximab, 3 mg/Kg) associated with low-dose weekly MTX (median dose 13 mg). Symptomatic treatment was stable during the observation. At every control the following parameters were evaluated: number of tender and swollen joints, pain VAS, General Health assessment VAS (GH VAS), ESR, CRP, haemoglobin level, DAS index, Health Assessment Questionnaire (HAQ), Short Form 36 (SF-36). Until now 37 patients completed a 6 months (6 infusions) whereas 11 patients completed a 12 months (10 infusions) course of treatment.

Results After 45 days a statistically significant improvement of all the parameters with the exception of CRP and haemoglobin level was observed. The long-term observation, up to month 6 (37 pts) and month 12 (11 pts), showed a statistically significant decrease of DAS, number of tender joints and pain VAS. The same statistically significant trend was observed also for parameters related to quality of life. The infusion was generally well tolerated. Major side effects leading to drug withdrawal were registered in 6 patients (hyperpyrexia in 2 patients, allergic reactions in 3 patients and pulmonary tuberculosis in 1 patient).

Abstract FRI0051 Table 1

	Basal T0 (45 pts)	After 2 infusions Day 45 (45 pts)	After 5 infusions Month 6 (37 pts)	After 9 infusions Month 12 (11 pts)
DAS	5.96	4.62*	4.7*	4.64*
HAQ	2.13	1.73*	1.78*	1.65*
Physical DIM SF-36	18.8	39.3*	39.68*	39.36*
Mental DIM SF-36	36.5	59*	52.19*	56.18*

*p < 0.05 Wilcoxon non parametric test.

Conclusion Monoclonal anti-TNF-alpha antibody in association with MTX induced a prompt and long-lasting (at least one year) symptomatic response with a significant decrease of disease activity and disability and an improvement of quality of life in a series of patients with rheumatoid arthritis refractory to traditional DMARDs.

FRI0052 TO EVALUATE ANTIBODIES ANTINUCLEAR (ANA) IN RHEUMATOID ARTHRITIS WITH INFlixIMAB TREATMENT

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Background

Objectives To examine the evolution of the ANA titre in patients with rheumatoid arthritis treated with infliximab (anti TNF-alpha).