in combination with methotrexate. Open studies with a few number of patients suggested that infliximab as monotherapy is also effective in active spondyloarthropathies.

Objectives To evaluate the efficacy of infliximab as monotherapy in patients with refractory and active spondyloarthropathy.

Methods Thirty-eight week, open, multicentric and prospective trial, in 42 patients with spondyloarthropathy, according to the ESSG and/or Amor criteria. All patients have disease duration of more than one year and persistent disease activity despite use of different drugs (NSAIDs, sulfasalazine, methotrexate or pamidronate). Infliximab is administered at a dose of 5 mg/kg, at 0, 2, 6, 14, 22 and 30 weeks. Clinical assessment was performed at these weeks at a week 38. Different clinical disease activity measures are performed, including BASDAI and patient global assessment of disease status. Disability is measured by BASFI and HAQ-Sp. ESR and CRP is used as laboratory parameters of inflammation.

Results Preliminary results at week 0, 2 and 6 in 10 patients (3F/7M): 8 AS patients and 2 undifferentiated spondyloarthropathy; mean age: 36 ± 7 yr, mean disease duration: 14 ± 6 yr are presented in this Table 1.

In all patients a significant improvement in clinical, functional and laboratory parameters were observed. This improvement was seen at week 2 (after the first dose) and is maintained at week 6.

Abstract OP0059 Table 1

	BASDAI (m $\pm$ sd)	BASFI (m $\pm$ sd)	GLOB ASSESS (m $\pm$ sd)	ESR (mm) (m $\pm$ sd)	CRP (mg/dl) (m $\pm$ sd)
Week 0	7.47 $\pm$ 1.05	6.80 $\pm$ 1.31	8.06 $\pm$ 1.09	51 $\pm$ 32	35.8 $\pm$ 29.3
Week 2	3.52 $\pm$ 2.44*	Not evaluate	3.97 $\pm$ 2.06*	18 $\pm$ 17*	4.5 $\pm$ 4.1*
Week 6	3.12 $\pm$ 1.43	3.16 $\pm$ 1.85	3.38 $\pm$ 1.79	11 $\pm$ 18	3.5 $\pm$ 3.1

*p < 0.01.

Conclusion Preliminary results of this open study show that infliximab provides a quick and significant clinical improvement in refractory spondyloarthropathies.

OP0063 THREE MONTHS RESULTS OF A DOUBLE-BLIND PLACEBO CONTROLLED, PHASE-III CLINICAL TRIAL OF INFILIXIMAB IN ACTIVE ANKYLOSING SPONDYLITIS

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Background Recently, patients with severe ankylosing spondylitis (AS) significantly improved upon treatment with the anti-tumour necrosis factor α (TNF α) antibody infliximab (RemicadeR) in an open pilot study (A&R June 2000). Therefore, a placebo-controlled trial was designed to prove that the administration of infliximab has a beneficial effect on the short and long term course of severe AS.

Objectives

Methods Seventy patients (47 men, 23 women) with a mean age of 39.2 years and proven AS (1984 New York criteria) in an

active stage of disease were included in the study. Active disease was defined as a Bath AS Disease Activity Index (BASDAI) > 4 and pain > 4 on a numeric rang scale (NRS). The patients were randomised into two groups of 35 patients each which received either infliximab in a dosage of 5 mg/kg i.v. or placebo. Infusions were given at week 0, 2 and 6 and then every 6 weeks until week 48. The BASDAI, BASFI (Functional Index), BASMI (Metrology Index), pain on a NRS, quality of life by the SF36 and CRP were measured. Patients with > 50% improvement of BASDAI was defined as a responder. The study started on August 15th 2000; the last patient was included on 19th October 2000.

Results The last patient has finished the placebo-controlled part of the study on January 25th 2001. Sixty-six patients have completed the three-months placebo-controlled period. One patient developed tuberculosis. The three-months-follow up data which are just being analysed are presented at the EULAR-Meeting in June 2001.

Conclusion The subjective therapeutic efficacy in some of the patients was impressive but the results of the ongoing analysis have to be awaited.

SAT0001 ROLE OF DETERMINATION OF SUCCINATE DEHYDROGENASE, MYELOPEROXIDASE, NA $\pm$ K $\pm$ ATP-ASE, 5'-NUCLEOTIDASE IN CELLS OF PERIPHERAL BLOOD OF ANKYLOSING SPONDYLARTHRITIS PATIENTS

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Background

Objectives To assess the value of determination Myeloperoxidase (MP), Na $\pm$ K $\pm$ AOPh-ase (ATPh-ase), 5'-Nucleotidase (5'-NT), Succinate dehydrogenase (SDG) in cells of peripheral blood of ankylosing spondylarthritis (AS) patients.

Methods We observed 30 AS patients and 30 healthy donors (HD) as control group. The activities of enzymes were determined by histochemical methods.

Results We observed increasing of ATPh-ase in neutrophils and lymphocytes, MP in monocytes, 5'-NT in lymphocytes, monocytes and neutrophils, decreasing of MP in neutrophils (p < 0,05). We observed the greatest increasing of ATPh-ase in neutrophils in 1st degree of AS activity, 5'-NT in all cells and MP in monocytes – in fast progressing AS. Level of SDG in lymphocytes in AS did not differ from HD. There were correlation between level MP in neutrophils and expressiveness of an anaemia (r = -0,41, p = 0,029). Reliable dynamics of enzymes activities were noted during the course of treatment. We revealed normalisation of MP in monocytes and neutrophils when the patients received indomethacin. There were decreasing of 5'-NT level at the treatment by NSAIDs and steroid hormones. There was correlation of clinical improvement with activity of 5'-NT in blood cells.

Conclusion The determination of MP, ATPh-ase, 5'-NT, but not SDG activities in blood cells can be used for improvement of quality of AS diagnostics and for control of treatment quality.