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THU0196 EFFICACY OF AND PREDISPOSING FACTORS FOR RESPONSE TO LEFLUNOMIDE (LEF) IN PATIENTS WITH RHEUMATOID ARTHRITIS (RA)

¹M Dougados, ²C Antoine, ²S Brin, ³P Emery, ⁴EM Lemmel, A Rodriguez de la Serna⁵, CA Zerbin⁶, ⁵P Van Riel. ¹Rene Descartes University, Hospital Cochin, Paris, France; ²Laboratoire Aventis, Paris, France; ³University of Leeds Research School of Medicine, Leeds, UK; ⁴Max Grundig Clinic, Buhl, Germany; ⁵University Medical Centre Nijmegen, Nijmegen, The Netherlands; ⁶San Pablo Hospital, Barcelona, Spain; ⁶Hospital Heliopolis, Sao Paulo, Brazil

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Background LEF is a new DMARD for the treatment of active RA in adults. Large phase III clinical trials have shown that LEF significantly improves the signs and symptoms of RA compared to placebo. LEF also significantly improved patient functional ability and individual health-related quality of life compared with placebo and methotrexate, and slowed radiographically assessed disease progression. In addition, LEF has an early onset of action, with a clinical response being seen by 4 weeks and a sustained response observed at up to 2 years.

Objectives To evaluate the efficacy of, and predisposing factors for response to LEF in a large multinational, multicenter, open-label cohort study at 24 weeks.

Methods Patients with active RA classified by a disease activity score (DAS >3.2) were enrolled and treated with LEF (100 mg loading dose x 3 days with 20 mg QD thereafter). The efficacy variables analysed at week 24 were the DAS 28 responder rate, the response rate according to ACR 20%, ACR 50% and ACR 70%, and change from baseline for both scores. All subjects who received at least one dose of study medication were included in the intent-to-treat with last observation carried forward analysis. At week 24, baseline data (including RA duration and ARA functional class) from patients who were classified as responders compared with non-responders at week 24 were analysed to determine predictive factors of response.

Results Of the 966 patients treated with LEF for 24 weeks, 720 (75%) were female with a mean age of 55 years (range 19-75). The mean duration of previous RA was 7.5 years with 62% patients first being diagnosed >2 years. The mean duration of morning stiffness was 2.1 h and 83% of patients tested positive for rheumatoid factor at baseline. For those patients who had previously had DMARD treatment (72%), the mean number of previous treatments was 2.6. At week 24, 78% of patients were responders according to the DAS 28 responder rate. The percentage of patient responders at week 24 for ACR 20%, ACR 50% and ACR 70% were 67, 36, and 10% respectively. At week 24, 13% patients fulfilled the disease remission criteria (DAS 28 ≤ 3.2). Of the patients, 35% and 50% were responders at week 4 and 8, respectively, and maintained efficacy until week 24. One hundred and ninety patients were withdrawn from the study (11% due to an adverse event, 3% for a lack of efficacy). ARA functional class 1 and RA duration >2 years were identified as predisposing factors for treatment response.

Conclusion This study confirms the efficacy of LEF in patients with RA. Further evaluation may suggest the clinical relevance of identified predisposing factors for treatment response.

THU0197 TUMOUR-ASSOCIATED ANTIGENS IN RHEUMATOID ARTHRITIS

¹P Athanassiou, ¹A Elezoglou, ²I Kostoglou-Athanassiou, ¹A Theodorou, ¹P Konstantopoulou, ¹A Kotrotsios, ³P Dimou, ¹G Vezyroglou. ¹Department of Rheumatology; ²Department of Endocrinology, Metaxa Hospital, Pireaus, Greece; ³Department of Biochemistry, Asklepieion Hospital, Voula, Athens

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Background Rheumatoid arthritis (RA) is characterised by aberrations of the immune system. Moreover, treatment of RA patients involves agents, which induce immunosuppression. However, it has not yet been clarified whether RA or its primary treatment predispose to the development of malignancy.

Objectives The aim was to investigate tumour-associated antigens and other markers of malignancy in patients with RA.

Methods Patients with RA, n = 38, aged 59.0 ± 2.0 years (mean ± SEM), duration of disease 8.1 ± 1.1 years were studied. Patients with osteoarthritis (OA), n = 38, were also studied. None of the patients had any known malignancy. All patients had a complete physical examination when entering the study. In all patients levels of haematocrit, haemoglobin, erythrocyte sedimentation rate, C-reactive protein, rheumatoid factor and alkaline phosphatase were measured. All patients were tested for positivity for antinuclear antibodies (ANA). In all patients levels of carcinoembryonic antigen (CEA), a-fetoprotein, b2-microglobulin, CA 15 - 3, CA 125 and CA 19 - 9 were measured.

Results In patients with RA haematocrit was 35.3 ± 0.5% (mean ± SEM), haemoglobin 11.2 ± 0.2 g/dl, C-reactive protein 54.7 ± 6.5 mg/l and rheumatoid factor 197.6 ± 34.9 iu/ml. In patients with OA haematocrit was 39.0 ± 0.7%, haemoglobin 12.4 ± 0.2 g/dl, C-reactive protein 23.4 ± 4.9 mg/l and rheumatoid factor 10.6 ± 0.2 iu/ml. In patients with RA and OA CEA levels were 1.4 ± 0.1 ng/ml and 2.2 ± 0.2 ng/ml, respectively (normal range <5.0 ng/ml, Student's t test p < 0.05). In RA and OA patients a-fetoprotein levels were 3.1 ± 0.2 ng/ml and 4.0 ± 0.3 ng/ml, respectively (normal range <8.6 ng/ml). In RA and OA b2-microglobulin levels were 1.7 ± 0.1 mg/l and 1.6 ± 0.1 mg/l, respectively. There was no difference in the levels of any of the specific tumour-associated antigens between the groups of patients with RA and OA. In RA and OA patients CA 15 - 3 levels were 19.1 ± 0.8 u/ml and 18.2 ± 1.0 u/ml, respectively (normal range <28 u/ml, p > 0.05). In RA and OA patients CA 125 levels were 9.5 ± 0.9 u/ml and 7.0 ± 0.5 u/ml, respectively (normal range <35 u/ml, p > 0.05). In RA and OA CA 19 - 9 levels were 9.3 ± 1.4 u/ml and 9.7 ± 1.3 u/ml, respectively (normal range <37 u/ml, p > 0.05).

Conclusion In RA patients CEA levels were found to be lower than those of OA patients, being however in the normal range for both groups. Levels of tumour-associated antigens were found to be in the normal range in RA and OA patients, no significant difference being observed between the groups. It appears that in RA no significant alteration of the levels of tumour-associated antigens is observed. Additionally, in the population of patients studied RA did not appear to predispose to the development of malignancy. More studies are needed in order to find the effect of RA and its primary treatment on the development of malignancy.