Conclusion ENBREL plus MTX remains safe and well tolerated. Improvement of disease activity is sustained even with reduced or discontinued doses of MTX and/or steroids.

REFERENCES

- 1 Kremer JM, et al. *Arthritis Rheum.* 2000;43:S270
- 2 Weinblatt ME, et al. *NEJM* 1999;340:253-9

FRI0080 LONG-TERM USE OF ENBREL® (ETANERCEPT) IN PATIENTS WITH DMARD-REFRACTORY RHEUMATOID ARTHRITIS

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Background Results have been previously presented from a long-term safety trial of ENBREL as monotherapy in adult patients with RA who had failed at least one DMARD. In this ongoing study, 628 patients have been followed for up to 4.3 years (median = 2.4 years) for a total of 1336 patient-years.

Objectives Continue to observe the long-term safety and clinical benefit of ENBREL.

Methods Patients were evaluated for disease activity using ACR criteria. Adverse event rates were compared with data from controlled studies.

Results 479 adult patients have received ENBREL as monotherapy for over 1 year, 420 for over 2 years, 164 for over 3 years, and 12 for over 4 years. Response has been sustained for the duration of therapy. At baseline, the median tender joint count was 31 and the median swollen joint count was 25. At 3.5 years, the median tender and swollen joint counts were 3 each, and 69% of patients had achieved the ACR 20, 50% the ACR 50, and 25% the ACR 70. Also at 3.5 years, 24% of patients had zero tender joints, 26% had zero swollen joints, and 15% had disability scores of zero. In addition, 59% of patients who were receiving corticosteroids at study start have decreased their steroid doses by a mean of 71%, 29% of patients have completely discontinued steroids, and only 5% have increased their steroid dose. Compared to events seen in controlled trials or in the normal adult population, no significant differences in rate or type of adverse events were seen in patients treated with ENBREL over time. Serious adverse events occurred at a rate of 0.13 per patient-year in the long-term database compared to 0.13 in ENBREL-treated patients and 0.20 in placebo patients in the controlled studies. Likewise, serious infections (associated with hospitalisation or IV antibiotics) occurred at a rate of 0.05 per patient-year in the long-term database compared to 0.04 in ENBREL patients and 0.05 in placebo patients in the controlled studies. The number of malignancies reported in ENBREL patients was similar to the expected number calculated from the National Cancer Institute SEER database (9 reported vs. 12.7 expected). No opportunistic infections have been observed.

Conclusion ENBREL as monotherapy continues to be safe and effective in patients with DMARD-refractory RA for over 4 years.

REFERENCE

- 1 Moreland LW, et al. *Arthritis Rheum.* 2000;43:S270

FRI0081 IMPROVEMENT OF DISABILITY IN RA PATIENTS WITH EARLY VS ESTABLISHED DISEASE AFTER TREATMENT WITH ENBREL® (ETANERCEPT)

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Background Functional health status declines and disability increases early in patients with RA, with half of affected patients developing moderate loss of functional ability within 2 years of diagnosis.¹ Early initiation of aggressive treatment has been suggested as a means to improve long-term outcomes.

Objectives To evaluate the impact of early therapy with ENBREL on disability.

Methods In this analysis, we compared the improvement in Health Assessment Questionnaire (HAQ) disability scores over 2 years in 207 patients with early disease (mean duration of RA was 1 year) to 563 patients with long-standing disease (mean duration of RA 12 years) who were treated with 25 mg ENBREL SC twice weekly.

Mean baseline patient characteristics in the early vs. late groups were similar, including HAQ (1.5 vs 1.6), number of tender (31 vs 32) and swollen (24 vs 26) joints, CRP (3.3 vs 4.4 mg/dL), presence of RF (87% vs 81%), and age (51 vs 53 years). Patients with early disease had been treated with fewer DMARDS (0.5 vs 3.3).

Results Patients with both early and late RA achieved rapid and sustained clinical responses and improvement in HAQ scores, but the magnitude of improvement in HAQ was greater in patients with early disease. At 2 years, mean HAQ scores declined from 1.5 to 0.6 in the early RA group and from 1.6 to 1.0 in patients with established disease. The proportion of patients who achieved zero HAQ scores was greater for patients with early disease (29%) compared to patients with late disease (14%) ($p < 0.001$).

Conclusion While patients with early or long-standing disease had significant improvement in disability with ENBREL therapy, patients with early disease had greater benefit. Aggressive therapy in patients with early RA has greater potential to improve disability as measured by HAQ than in patients with more established disease who have failed multiple DMARDS.

REFERENCE

- 1 Wolfe F. A Reappraisal of HAQ disability in rheumatoid arthritis. *Arthritis Rheum.* 2000;43:2751-61

FRI0082 EFFECT OF HYDROXYCHLOROQUINE THERAPY ON CARTILAGE INJURY IN RHEUMATOID ARTHRITIS

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Background Better methods for assessing articular injury are needed to monitor efficacy of disease-modifying therapy in rheumatoid arthritis (RA).

Objectives The purpose of this study was to measure serum levels of cross-linked peptides from the C-telopeptide of type II collagen (col²CTx) during treatment of patients with RA.