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A central role of interleukin-6 (IL-6) as key player in the pathophysiology of NMOSD, is strongly supported by the significant reduction in risk of relapse as previously demonstrated in the SAkuraSky study of the IL-6R inhibitor satralizumab for treatment of NMOSD as an add-on therapy. Here, we report the results of additional analyses (ClinicalTrials.gov number, NCT020728884).

83 patients meeting NMOSD diagnostic criteria with/without AQP4-Ab and at least two relapses in the last 2 years were randomly assigned to receive satralizumab 120 mg subcutaneously or placebo at week 0, 2 and 4 and every 4 weeks thereafter, added to stable immunosuppressant treatment. The primary endpoint was time to first protocol-defined relapse. Pre-specified additional analyses included efficacy in AQP4-Ab positive vs. negative subgroups, and effect on annualized relapse rate (ARR). Hazard ratios (HRs) were based on Cox proportional hazards model.

Satralizumab added to baseline treatment significantly reduced risk of protocol-defined relapse by 62% vs placebo; HR, 0.38; 95% confidence interval (CI), 0.16 to 0.88; P=0.0184. Pre-specified additional analyses showed a 79% relapse risk reduction with satralizumab vs placebo in AQP4-Ab(+) patients (n=55; HR, 0.21; 95% CI, 0.06 to 0.75) and 34% in AQP4-Ab(-) patients (HR 0.66; 95% CI, 0.20 to 2.24). In the overall study population, ARR was 0.11 (95% CI, 0.05 to 0.21) when treated with satralizumab vs 0.32 (95% CI, 0.19 to 0.51) with placebo.

Treatment with satralizumab as add-on to baseline immunosuppressant therapy significantly reduced relapse risk, particularly in AQP4-Ab(+) NMOSD patients.

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Fingolimod for Relapsing-Remitting Multiple Sclerosis: The Experience from Saudi Arabia

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Fingolimod (Gilenya, Novartis pharmaceuticals) is the first oral disease-modifying therapy for reducing the frequency of clinical relapses and delaying disability progression in patients diagnosed with relapsing-remitting multiple sclerosis (RRMS). In this study, we aim to evaluate the outcome of Saudi patients with active RRMS treated with fingolimod and compare the result with other studies.

We conducted a retrospective multicenter observational study involving 100 patients with RRMS at King Abdulaziz Medical City in Jeddah and Riyadh, Saudi Arabia. The inclusion criteria consisted of patients above the age of 18 years, diagnosed with RRMS according to the revised McDonald criteria, and are currently receiving or received fingolimod treatment in the past for a minimum of six months.

The mean baseline expanded disability status scale (EDSS) score was 2.95±2.58 (range 1-7; median 1.75). The mean EDSS score at last follow up was 2.95±2.65 (range 1-10; median 2.00). The mean annualized relapse rate (ARR) was significantly reduced from 1.24±1.39 at baseline to 0.43±1.15 at the last follow-up (P = 0.001). In addition, radiological activity was significantly improved at follow-up magnetic resonance imaging (MRI) studies when compared to the baseline.

Our multi-center study provides further evidence on the efficacy of fingolimod in reducing clinical and radiological disease activity in patients with RRMS. The reduction in relapse rate, stabilization of EDSS score, and improvement in MRI images were similar to other observational studies conducted in different countries worldwide. Fingolimod appears to be a well-tolerated for our MS population.

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The Use Natalizumab in Multiple Sclerosis Patients During Pregnancy is Safe and Prevents Disease Reactivation

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Data of the use of natalizumab during pregnancy is limited in Multiple Sclerosis (MS) patients. We aimed to assess the effectiveness and safety of natalizumab in MS during pregnancy.

The cohort constituted 3 groups; patients continued natalizumab during pregnancy till 28th gestational week (group 1), patients discontinued natalizumab before pregnancy (group 2) and a control group included women who did not get pregnant (group 3). Relapses and MRI new T2/ gad-enhancing lesions during pregnancy and at one-year post delivery were compared.

68 patients were identified. At baseline, there were no significant differences across the three groups in mean age (p = 0.07), mean age at onset (p = 0.44), mean disease duration (p = 0.21), annualized relapse rate (p = 0.27) and MRI measures (p = 0.25). The mean number of natalizumab infusions was 44 ± 26.05. During pregnancy, no relapses occurred in group 1 while four patients (28.6%) sustained relapses in group 2 (p = 0.03). At last follow-up visit, annual relapse rate was significantly higher in group 2 (0.75 ± 0.51), compared to groups 1 & 3 (0.14 ± 0.36 & 0.05 ± 0.22; p < 0.001) respectively. The proportion of patients with MRI activity was significantly higher in group 2 compared to groups 1 and 3 (50%, 7.1%, and 2.5%; p = 0.03). Abortion rate was not statistically significant between group 1 and 2 (p = 0.47) and no fetal malformation was observed.

Patients who continued using natalizumab during pregnancy remained in remission. The use of natalizumab during pregnancy was safe.

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Pregnancy Outcome in Multiple Sclerosis Patients Exposed to Disease Modifying Therapies

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