

1 ABSTRACT

Title

Evaluation of the effectiveness of the abatacept (ORENCIA®) intravenous and subcutaneous formulation Patient Alert Cards in patients with rheumatoid arthritis in a sample of European Economic Area countries.

Keywords

Risk minimization; Orencia; abatacept; Patient Alert Card; effectiveness evaluation

Rationale and Background

Patient Alert Cards (PACs) for intravenous (IV) and subcutaneous (SC) abatacept (ORENCIA®) are primarily used to inform patients about the risk of infections. The effectiveness of the PACs in rheumatoid arthritis patients was evaluated as part of a post-marketing commitment to the European Medicines Agency, as described in the European Union Risk Management Plan.

Study Objectives

The primary objectives of the study were to assess awareness, distribution, utilization, utility, knowledge, comprehension and behaviour by patients and healthcare professionals (HCPs), and correlate responses reported by patients with clinical/safety outcomes in the same patients.

Study Design

Non-interventional observational study consisting of cross-sectional surveys of rheumatologists/nurses and patients, and a retrospective chart review.

Setting

The study was conducted in France, Germany, Spain, Sweden and the United Kingdom.

Subjects and Study Size, including Dropouts

The study aimed to recruit 400 patients and 80 HCPs. Of 318 patients identified as potentially eligible, 190 completed the survey and 181 participated in the outcomes study. Of 320 HCPs interested to participate, 79 (50 physicians/29 nurses) completed the survey.

Data Sources

Patient questionnaires were completed online or on paper. HCP questionnaires were only available online. Clinical retrospective data from patients were abstracted and entered into the electronic case report form.

Results

Patient Survey

A total of 60% of patients were aware of the PAC, of whom 95% received (mainly through specialist nurses [45%] or via the medication box [31%]) and 84% had read the material. Knowledge about the risk of infections was higher among patients who received the PAC

compared to those who had not (64% vs. 46%, $p = 0.013$). The mean level of utility of the PAC was 61%. Two-thirds of patients reported that HCPs informed them about the side effects of Orencia.

HCP Survey

A total of 90% of HCPs were aware of the PAC and 68% had accessed the material, of whom 72% had read it. The PAC was mainly provided by nurses (67%). Knowledge about the risk of infections was demonstrated in 91% of HCPs who had access to the PAC versus 73% of those who did not ($p = 0.053$). The mean level of utility of the PAC was 71%. Most HCPs informed patients about the side effects of Orencia (96%).

Clinical Outcomes Study

The percentage of patients with infections leading to hospitalisation increased as the global score of understanding and implementation of the PACs (from the patient survey) decreased: 3% for scores $\geq 67\%$, 5% for scores 34-67% and 8% for scores 0-33%. However, with few patients experiencing infection, the correlation was not statistically significant.

Conclusion

The results are consistent with the objectives of the study and support the effectiveness of the Orencia PAC for its intended purpose. At present, no modifications to the content of the PAC are proposed. The study results suggest that distribution of the PAC to patients could be improved, despite already being included inside the Orencia product packaging, and that nurses should be the target of any strengthened distribution efforts, where feasible, emphasizing the need to discuss the information contained in the PAC with the patient as well as providing it for both the SC and IV formulations.