

ABSTRACT

Title	Use of Intravitreal JETREA in Clinical Practice: A European Prospective Drug Utilisation Study (TG-MV-017)
Keywords	Vitreomacular traction, ocriplasmin, vitreolysis, drug-utilisation, drug-safety
Rationale and Background	Standard treatment of vitreomacular traction (VMT) is pharmacologic vitreolysis with ocriplasmin (JETREA) or vitrectomy. JETREA is the first agent approved in Europe for the pharmacological treatment of VMT. As part of JETREA risk management plan (RMP), a post-authorisation safety study (PASS) was requested by the European Medicines Agency (EMA), to document the real-world patterns of utilisation, and to assess the effectiveness of the risk minimisation measures
Research Question and Objectives	To document JETREA utilisation patterns in real-life clinical practice To assess the effectiveness of the risk minimisation measures (<i>i.e.</i> the patient educational material [PEM] provided prior to the administration of JETREA)
Study Design	This PASS is a European, multicentre, observational study of patients with VMT, on which ophthalmologists independently decided to administer JETREA. These patients were offered participation in the drug utilisation study (DUS). Patients who consented to participate in the DUS were also invited to participate in the Patient Educational Material Evaluation Survey (PEMES)
Setting	The DUS eligible patients were selected from 29 sites in Germany, the United Kingdom, Spain and Italy. Site selection was designed to provide representative data across Europe
Subjects and Study Size, Including Dropouts	A sample of 300 DUS patients was planned, to incorporate off-label use and medication errors rate of 5% and 95% confidence interval (CI) width of 5. Based on the assumption that 85% of patients would demonstrate appropriate awareness and understanding of the PEM, a sample of 75 patients would allow the lower bound of the 95% CI to be equal to equate 76.9%
Variables and Data Sources	At the JETREA Pre-injection Assessment, data was collected on patient demographics, medical history and concurrent diseases, ocular intervention history and current ocular status, including indication for JETREA use. At the JETREA Injection Visit, the date of injection, the eye treated, administration details, anticipated treatment plan and utilisation information (including off-label use and medication errors) were collected. Patients who participated in the PEMES, were invited to complete a survey to assess their level of awareness and understanding of the PEM received prior to JETREA. The study investigators were also requested to report adverse events (AEs) suspected to be related with JETREA according to the standard reporting procedures in their country

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Results	A total of 301 DUS patients treated with JETREA and 51 patients who completed PEMES were included in the final analysis. JETREA was used according to the recommendations in the Summary of Products Characteristics (SmPC), and post-injection monitoring plans were scheduled in the majority of patients (90% or more). A minority of the JETREA patients presented at least one indicator of off-label use (4.3%) or medication error (9.3%). Almost half (49.0%) of the PEMES Respondents demonstrated appropriate awareness and understanding of the PEM (measured by an awareness score [AWS] higher than 85%), with 64.7% demonstrating an AWS higher than 75%
Discussion	The evidence generated on the patterns of utilisation of JETREA, demonstrate compliance to SmPC recommendations and did not reveal any safety concerns with JETREA use in routine practice. The study findings also indicate that JETREA's PEM is effective in informing patients on the use and possible effects of JETREA treatment
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