Citrato de fentanilo oral transmucosa en el tratamiento del dolor irruptivo en pacientes con cáncer en España: resultados del estudio EDIPAD [

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text (article)

Analítica

Introduction: Breakthrough pain refers to a sudden and severe painful outbreak that develops over a chronic pain controlled with opioids. OTFC is a drug that has been recently launched in our country, specifically developed for the management of this type of pain. After its launching in 2001, a post-authorization observational study was considered in order to assess its safety and tolerability. Collection of data regarding the effectiveness of OTFC was also considered, as well as their comparison with data obtained prior to the baseline visit for other therapies different to OTFC. Methods: Three hundred and twelve cancer patients with chronic pain controlled with opioids were recruited for the study. They presented breakthrough pain episodes and were followed-up for one month, with weekly control visits. Two hundred and ninety five patients were eligible for the safety and tolerability study of OTFC (safety population). On the other hand, 138 patients were assessed in terms of effectiveness, since they fulfilled the inclusion and exclusion criteria of the study and had received other therapies different to OTFC prior to the baseline visit. The following variables were determined: decrease of pain severity after the administration of therapy with an analogical visual scale scoring from 0 to 10, time elapsed until the beginning of pain relief and maximum relief after the administered treatment. Results: Safety: Of the 295 assessed patients, 59 (20%) had some adverse reaction. All of them were mild or moderate. No severe adverse reactions were notified during the study period. The most frequently reported adverse reactions were gastrointestinal effects, followed by CNS disorders (somnolence, hallucinations, confusion and dizziness) that are typical of treatment with opioids. Effectiveness: After the administration of OTFC in the last visit (+ 30 days), the time elapsed until the beginning of pain relief was significantly lower than the time elapsed after the administra

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Baratz Innovación Documental

- Gran Vía, 59 28013 Madrid
- (+34) 91 456 03 60
- informa@baratz.es