Patients and Methods

We designed a prospective open-label single-center uncontrolled study. Consecutive patients with Hurley stage II disease presenting our department were recruited from August 2016 to August 2018. Patients on systemic medications or those who were candidates for these drugs were excluded. The fistulous tract was chosen based on its size (less than 25 mm on ultrasound examination) and degree of inflammation (at least one flare-up in the three months before inclusion). We selected a single fistula per participant. We considered only chronic fistulous lesions, defined as those present for at least one month. Patients were treated with a single injection of ILT, that is, applying the drug inside the fistulous tract. If the lesion had a draining point, we used it as the injection place; if not we created our own following the clinical length of the lesion. In doubtful cases we used ultrasound to be sure the triamcinolone was injected inside the lesion and not in the surrounding tissue. Other topical treatments, such as resorcinol 15% or topical clindamycin 1%, as well as surgical treatments, were allowed for treating lesions located in areas of the body other than the included fistula.

Each patient was evaluated at two times points (at day 0 and day 90). The included lesion was marked and a clinical photograph taken at every visit to enable its identification at follow-up.A single dermatologist (JCP) performed all ultrasound examinations using a device with a high-frequency linear probe (MyLab 25 Gold; Esaote, Genoa, Italy;18 MHz). Injections were performed under sterile conditions, using a 1 mL syringe and a 25-gauge needle. Triamcinolone (Trigon, 40 mg/mL; Bristol-Myers Squibb, Anagni, Italy) was injected into the selected fistula (if the lesion had a draining point, we used it as the injection place; if not we created our own following the clinical length of the lesion), with no need for concomitant local anesthesia.

Demographic and HS-related variables were age, tobacco use, body mass index (BMI), age of HS onset, Sartorius scale²³, quality of life (Dermatology Life Quality Index, DLQI), and location and duration of the treated lesion. We also recorded clinical and ultrasound findings,

such as clinical resolution, ultrasound resolution, clinical size, ultrasound length and diameter, and color Doppler activity at baseline and day 90. Additional variables collected at baseline and at 90 days were the presence of erythema, edema, suppuration, pain and pruritus, along with treatment-related adverse events, especially the occurrence of cutaneous atrophy and/or pigmentation changes. Erythema, edema and suppuration were measured on a scale from 0 to 4, as proposed by Riis et al ¹⁰ for HS, where 0 represented normal-appearing skin in all aspects and 4 represented dark-red erythema, pronounced edema respectively. Pain and pruritus were assessed on a 10 cm visual analog scale (VAS; 0 =no pain/pruritus;10 = the worst pain/pruritus imaginable).

The institutional review board of the University General Hospital of Alicante approved the trial, and the Spanish Agency of Medicines and Medical Devices agreed with its classification as a post-authorization study. All participants gave informed consent to take part in the study.

Statistical Analysis

We compared mean values using the Student's t test for paired samples, while we used the chisquare test to analyze qualitative variables. Statistical tests were performed at a two-tailed significance level of 0.05, using SPSS version 19 (SPSS Inc, Chicago, IL, USA).