Effect of episil® oral liquid on oral mucositis severity and duration in HSCT patients

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INTRODUCTION

episil® oral liquid is a medical device indicated for the management and relief of pain caused by oral mucositis. It is a lipid-based liquid that spreads on the mucosal surface, where it transforms into a highly bioadhesive film which mechanically protects the damaged mucosa. We studied the effects of episil® plus standard of care (SOC) versus SOC alone on oral mucositis in patients receiving conditioning treatment for hematopoietic stem cell transplantation (HSCT).

OBJECTIVES

The aim of the study was to investigate the severity and duration of oral mucositis symptoms, as well as the safety and tolerability of episil®.

PATIENTS & METHODS

This was an open-label parallel-group study at 12 sites across 4 countries. Patients scheduled for myeloablative or intense reduced-intensity conditioning treatment followed by HSCT (n=116) were randomized 1:1 to SOC (which included basic oral hygiene) or SOC plus episil® treatment. episil® treatment comprised 3 pump strokes and was administered 3 times a day. Treatment with SOC or SOC plus episil® started on the first day of conditioning and lasted for 28 days. HSCT was done after 1-7 days of conditioning.

CONCLUSION

episil® had positive effects on oral mucositis severity and duration in patients receiving conditioning treatment for HSCT (PP population). In addition, episil® was well tolerated in this patient group.

REFERENCES


episil® is a registered trademark of Camurus AB, Sweden.

Research support provided by Camurus AB, Sweden.

www.camurus.com
www.episil.net

RESULTS

Of the 109 patients (median age 50 years) who received study treatment (intention-to-treat [ITT] population), 23 were excluded from the per-protocol (PP) population because of inadequate compliance (≤50% of study days with 100% compliance). Oral mucositis incidence was 76-77% in both treatment groups. Overall, the incidence and severity of oral mucositis were considerably lower than anticipated and 23% did not have any symptoms as graded by the WHO toxicity score at all.

AUC(0-28 days) for WHO Oral Toxicity Score, which reflects oral mucositis severity across the 28 days of treatment, was significantly lower for SOC plus episil® than for SOC alone in the PP population (adjusted mean 0.5 versus 0.7, p=0.028), but not in the ITT population (adjusted mean 0.7 versus 0.7, p=0.889).

Symptoms of oral mucositis as assessed by the WHO oral toxicity scale were generally observed to be mild for both treatment groups. There was a trend of gradual worsening of symptoms and increasing number of patients with WHO toxicity scores above zero during the first 14 days of the study. From Day 15 to 28, the average WHO toxicity score was observed to stabilise and then slowly decrease over time. There was a tendency of faster decrease of WHO scores in SOC + episil group than in SOC group in the ITT population, and also lower average WHO scores in SOC + episil group compared to SOC group in the PP population.

Mean duration (days) of oral mucositis was also significantly reduced in the SOC + episil® group compared with SOC alone in the PP population (5.5 versus 10 days, p=0.015), but not in the ITT population (8 versus 10 days, p=0.202).

SOC plus episil® was safe and well tolerated, with an adverse event (AE) profile comparable to that of SOC alone. Local tolerability of episil®, assessed as AEs associated with the oral cavity, was good, with 1 AE in the SOC plus episil® group (versus 2 AEs in the SOC alone group). There were 5 adverse device effects (ADEs), the most common of which was vomiting (3 events). There were no serious ADEs.

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A hazard ratio (HR) of 2.2 implies a 120% higher chance of achieving a zero WHO score at a particular day

Median duration of oral mucositis was also significantly reduced in the SOC plus episil® group compared with SOC alone in the PP population (5.5 versus 10 days, p=0.015), but not in the ITT population (8 versus 10 days, p=0.202).

SOC plus episil® was safe and well tolerated, with an adverse event (AE) profile comparable to that of SOC alone. Local tolerability of episil®, assessed as AEs associated with the oral cavity, was good, with 1 AE in the SOC plus episil® group (versus 2 AEs in the SOC alone group). There were 5 adverse device effects (ADEs), the most common of which was vomiting (3 events). There were no serious ADEs.