Treatment of oral mucositis pain by a bioadhesive barrier forming lipid solution.

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Objectives
Oral mucositis is a common side-effect of radiotherapy and chemotherapy of cancer. It is frequently a painful condition with ulceration of the mucous membranes and opportunistic infections in the mouth. In severe cases, it can be extremely painful and may necessitate hospitalization for oral pain medication and parental nutrition or even interruption of radiotherapy, which will complicate the final results. Development of a locally acting analgesic product with long effect duration would improve the wellbeing of a large group of cancer patients.

The current study investigated intra-oral pain intensity before and up to eight hours after intra-oral administration of a bioadhesive barrier forming lipid solution. The study included treatment using lipid solution both with and without the active ingredient benzoylamine.

Methods
- Multicentre, randomized, double-blind, single-dose, cross-over study
- More than 24 hours wash-out period between treatments
- Patients undergoing radiation therapy for treatment of head and neck cancer (N=38)
- Patients having oral mucositis of grade 2 or above (WHO grade) in week 3 to 4 of radiotherapy
- Assessment of oromucosal pain intensity (0-10 Likert pain score) before and 5, 30, 60, 1, 2, 3, 4, 6, and 8 hours after dosing.
- Treatments:
  - CAM2028 with benzoylamine
  - CAM2028 without benzoylamine (Episl®)
- Objectives
  - To demonstrate at least 6 h analgesic effect of a single dose
  - To assess safety and tolerability

Results
Evaluations of pain intensity versus time demonstrated an immediate treatment effect of the bioadhesive and barrier forming lipidsolution (see Figure 1). The maximum effect (mean 40% pain reduction) was reached after 1 hour and was maintained up to 8 hours. Similar treatment effects were obtained with and without benzoylamine.

The product was safe and well tolerated with no treatment-related adverse events.

Conclusions
CAM2028 provides an immediate and significant treatment effect maintained up to 8 hours post treatment. This relates to the effective protection of the oromucosal surfaces provided by the in situ barrier forming lipid solution. The unique bioadhesive and film-forming properties of CAM2028, which have been documented in a separate paper (1a clinical study), isolate the sensitive inadusted mucosa from external irritation. In contrast to other barrier forming products and standard therapy, assessed under similar clinical protocol, CAM2028 (Episl®) provides a statistically and clinically significant pain reduction for patients suffering from oral mucositis.

References

For more information, please visit www.camurus.com
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