

## A double blind placebo- controlled trial evaluation of sucralfate mouthwash for prophylaxis of chemotherapy-induced mucositis

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**Background and Aims:** Treatment of cancer is increasingly more effective but is associated with short and long term side effects. Oral side effects remain a major source of illness despite the use of a variety of agents to prevent them. One of these side effects is oral mucositis (mouth ulcers).

**Methods:** 51 patients with malignant disorders, who were going to receive 5-fluorouracil containing chemotherapy, were enrolled in a double-blinded, placebo-controlled randomized clinical trial. Sucralfate mouthwash (15 mg/100ml) or placebo was administered after chemotherapy. Patients were instructed to use the suspension as a mouthwash four times daily from the beginning of the chemotherapy cycle. A questionnaire consisting of demographic parameters, medical status, quality of life survey and mucosal injury scoring table was completed for each patient at Day 1, 3 and 6 after chemotherapy.

**Results:** 25 patients were randomized to the sucralfate treatment and, 26 to the placebo treatment. The median age for all patients was 56 years, and 16 (30.8%) of the patients were female. In three first days after administration in sucralfate group: 72% patients showed no ulcers, pain and redness in their mouth. 12% had mild mucositis and 8% showed severe mucositis. In placebo group: 38.5% patients showed none of any ulcer, redness and pain. 15.2% patients had mild and 42.2% had severe mucositis. In three second days after administration in Sucralfate group: 76% patients had no pain, no ulcer and no redness. 16% patients had mild mucositis and none of them had severe mucositis. In placebo group: 42.3 % showed no pain, no ulcer and no redness. 24% patients had mild mucositis and 30.6% had severe mucositis.

**Conclusions:** Sucralfate mouthwash was effective in the prophylaxis of chemotherapy -induced mucositis.

**Keywords:** Sucralfate; Mouthwash; Mucositis; Prophylaxis