



# PREVENTION AND TREATMENT OF ORAL MUCOSITIS IN PATIENTS TREATED WITH CHEMORADIO THERAPY WITH HEAD AND NECK CANCER



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## INTRODUCTION

There is a large body of evidence data regarding the benefit of supersaturated calcium phosphate solution (SCPS) in treatment of oral mucositis in haematology malignances, after bone marrow transplantation<sup>1</sup>. For patients treated with head and neck cancer (HNC) treated with chemoradiotherapy (CRT), there are few data available to evaluate the benefit of this drug.<sup>2</sup>

## PURPOSE

Evaluate the benefit of SCPS in prevention and treatment of oral mucositis in patients treated with CRT for HNC.

## MATERIAL AND METHODS

- Unicentric, prospective, non randomized clinical study with an unblinded sample of allocation for convenience.
- 2 arms: Experimental arm with SCPS vs Control arm with mouthwash of lidocaine and bicarbonate (LB).
- Both arms received prophylactic nystatin mouthwash.

ELIGIBILITY CRITERIA	EVALUATION CRITERIA
Pathologic proven squamous cell carcinoma HNC Stage III and IVa Concomitant CRT No previous chemotherapy IMRT, 60 to 69,96 Gy. Cisplatin (100mg/m <sup>2</sup> ), 3 Cycles Patients with competence for self-care Informed consent form for each patient	TIME TO MUCOSITIS G≥1- PREVENTION CRITERIA REDUCTION AT LEAST ONE GRADE OF MUCOSITIS DURING QRT AND 4 WEEKS AFTER QRT- TREATMENT CRITERIA
	SECONDARY ENDPOINTS: PAIN CONTROL (MORPHINE) TUBE FEEDING INWARD DUE TO MUCOSITIS

	Monday	Tuesday	Wednesda y	Thursd ay	Frida y		Monda y	Tuesda y	Wednesd ay	Thursa day	Frida y
Week 1	X		X	X	X	Radiation Oncology Consult Medical Oncology Consult Nurse Consult	Week 1	X	X	X	X
Week 2	X		X	X	X		Week 2	X	X	X	X
Week 3	X		X	X	X		Week 3	X	X	X	X
Week 4	X		X	X	X		Week 4	X	X	X	X
Week 5	X		X	X	X		Week 5	X	X	X	X
Week 6	X		X	X	X		Week 6	X	X	X	X
Week 7	X		X	X	X		Week 7	X	X	X	X
4 weeks after ending QRT			X	X		4 weeks after ending QRT			X	X	

Table 1. Physicians and nurse consults before mucositis diagnosed, both arms.

Table 2. Once weekly physicians consult and daily nurse consults to patients, both arms, when mucositis diagnosed

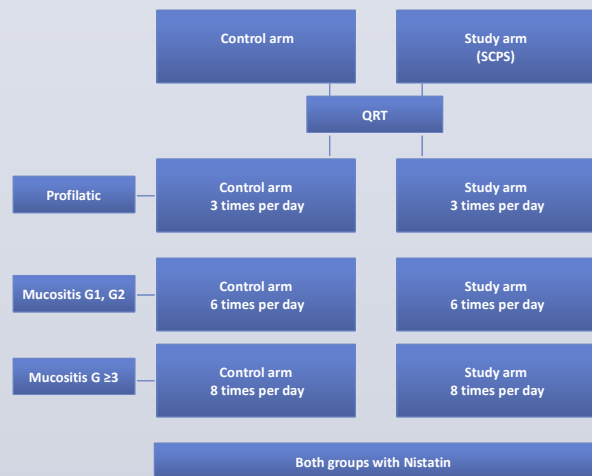


Fig.1 Clinical Study Design

2 groups, control arm and study arm, and the posology used for prevention and treatment, according to the grade of mucositis.  
Nystatin: prevention of fungal infection, in both arms.

To evaluate the mucositis it was used the Common Terminology Criteria for Adverse Events (CTCAE) version 4.0.  
For statistical analysis it was used the following tests: Wilcoxon-Mann Whitney, Fisher, Logrank and Pearson.

## RESULTS

General Data		Control arm (n=17)	Study arm (n=17)	p
Age, years	Median (Min – Max)	56 (17-67)	61 (38-68)	0.101
Gender, n (%)	Female	1 (6%)	0	1.000
	Male	16 (94%)	17 (100%)	
Tumor site, n (%)	Nasopharynx	6 (35%)	4 (24%)	0.553
	Oropharynx	3 (18%)	5 (29%)	
	Hypopharynx	2 (12%)	5 (29%)	
	Laringe	3 (18%)	1 (6%)	
	Oral cavity	1 (6%)	2 (12%)	
	Maxillary Sinus	1 (6%)	0	
	Primary Unknown	1 (6%)	0	
Surgery, n (%)	NO	10 (59%)	11 (65%)	0.785
	YES	7 (41%)	6 (35%)	
Dose of Radiotherapy, n (%)	60 Gy	2 (12%)	0	0.552
	66 Gy	4 (23%)	5 (29%)	
	69.96 Gy	11 (65%)	12 (71%)	
Number of cycles of Cisplatin	Median (Min – Máx)	3 (2-3)	3 (2-3)	0.426

Table 3. General informations, both arms.

	Control arm (n=17)	Study arm (n=17)	p
Time to diagnose Mucositis grade ≥1 (weeks) PREVENTION	Median (Min – Máx) 3 (2-6)	4 (2-6)	0.046

	Control arm (n=17)	Study arm (n=17)	p
Reduction at least one grade of mucositis TREATMENT	7/17 (35%)	14/17 (87.5%)	0.00386

	Control arm (n=17)	Study arm (n=16)	p
Reduction at least one grade of mucositis 4 weeks after ending CRT TREATMENT	6/17 (35%)	14/16 (87.5%)	0.00386

Tables 4, 5 and 6. Prevention and treatment of mucositis, in both arms  
Superiority of SCPS for treatment with a very statistic p value.

Note: table 6, study arm with 16 patients because one of them don't change the grade of mucositis, 4 weeks after CRT.

There were no statistic differences in tube feeding, use of morphine or inward, in both arms.

## CONCLUSIONS

Due to logistic reasons this was a non-randomized and an unblinded study; however, SCPS was superior to mouthwash LB on prophylactic and treatment of mucositis in patients with HNC.

We also conclude the importance of nurse care assistance in these preventions, optimizing a better selfcare to patients and also a better quality of life during and after CRT.

## REFERENCES

- CTCAE, V.4.0; 2. NCCN guidelines for Head and Neck 2014 3. Markievicz, et al. Treating oral mucositis with a supersaturated calcium phosphate rinse: comparison in control patients undergoing allogeneic hematopoietic stem cell transplantation. Support Care Cancer 2012 (20): 2223-2229

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