Cetuximab/RT versus concomitant CT/RT with or without induction TPF in locally advanced H&N squamous cell carcinoma. Preliminary toxicity results of a randomized, 2x2 factorial, phase II-III study (NCT01086826)

Gruppo di Studio sui Tumori della Testa e del Collo (GSTTC) - Italy

MG Ghi, A Paccagnella, D Ferrari, P Foa, F Nolè, F Morelli, G Azzarello, C D'Ambrosio, C Casanova, M Guaraldi, G Mantovani, C Rossetto, A Bonetti, S Siena, A Buffoli, H Koussis, G Pieri, A Gava, I Floriani.

Presented at the 2012 ASCO Annual Meeting. Presented data is the property of the author.

ASCO Annual '12 Meeting

Participating centres

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IEO Milano	Belluno	Tolmezzo
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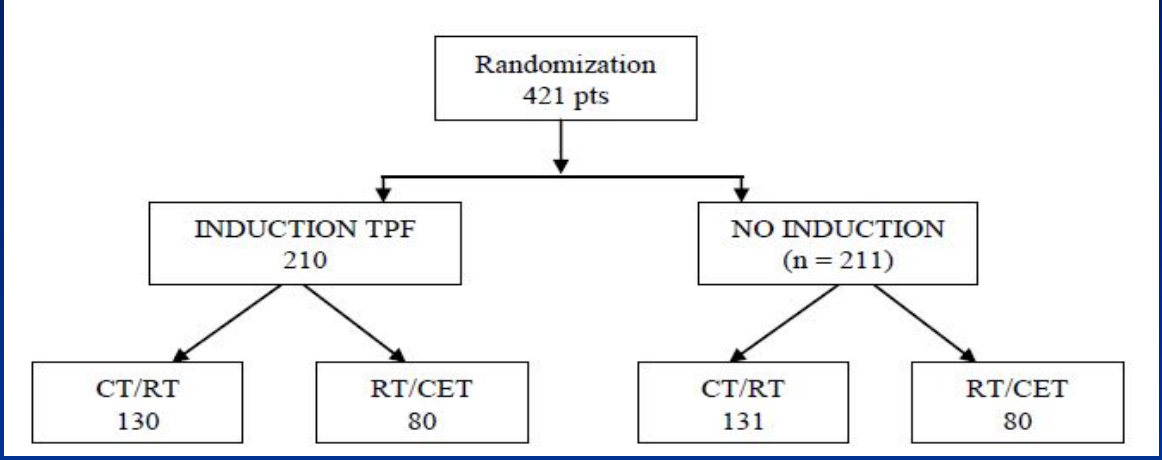
EVALUABLE PATIENTS

- Accrual completed from 45 Italian Centres in April 2012 (421 patients)



- 348 patients are already evaluable for toxicity during the planned concomitant treatments (CT/RT vs cetuximab/RT)

CT/RT VS RT/CETUXIMAB: IN-FIELD TOXICITY ON 348 ALREADY EVALUABLE PATIENTS

	CT/RT (n=215) %	RT/cetuximab (n=133) %	p value
Mucositis any grade	78	76	0.63
Grade 3	37	35	0.79
Grade 4	4	2	0.45
In-field skin toxicity any grade	59	69	0.05
Grade 3	13	20	0.07
Grade 4	1	1	0.58

COMPLIANCE WITH CONCOMITANT TREATMENTS

	CT/RT n=215	RT/cetuximab n=133	p value
Chemo/cetuximab completition - no modification	93% 75%	81% 50%	<0.01
RT completition - no modification	96% 60%	94% 49%	0.14
Median dose RT, Gy (range)	70 (8-70)	70 (14-70)	0.32
Median duration, weeks (range)	7 (1-13)	8 (1-14)	<0.01
Pts with RT interruption > 3 d	32%	38%	0.22
RT modification due to acute toxicity (%)	37%	40%	0.58

Original article

Effects of fluconazole in the prophylaxis of oropharyngeal candidiasis in patients undergoing radiotherapy for head and neck tumour: results from a double-blind placebo-controlled trial

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Effects of fluconazole in the prophylaxis of oropharyngeal candidiasis in patients undergoing radiotherapy for head and neck tumour: results from a double-blind placebo-controlled trial

Fluconazole is recommended in the prophylaxis of oropharyngeal candidiasis (OPC) in patients undergoing radiotherapy for head-neck tumours; however, the actual effectiveness of fluconazole in this setting remains unclear. Adult patients with cervico-cephalic carcinoma submitted to radical or adjuvant radiotherapy were randomized to 100 mg fluconazole ($n = 138$) or matched placebo ($n = 132$) oral suspension once daily from the sixth session of radiotherapy up to the end of treatment. The final analysis of the investigation showed a higher

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