

# Clinical trials of Induction chemotherapy for Head and neck cancer in all type of patients

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## 1 docetaxel based induction CT

Trial	Treatments	Patients	Trials design and methods
<b>TPF vs no induction chemotherapy</b>			
<b>Hitt (TPF) , 2005</b> <i>ongoing</i> n=NA follow-up:	induction chemotherapy with docetaxel + 5-FU+ cisplatin , TPF induction with docetaxel, cisplatin, 5-FU followed by chemoradiotherapy versus chemoradiotherapy	patients with locally advanced, unresectable SCCHN	open Spanish
<b>AVENTIS-DFCI-04006</b> <i>ongoing</i> [NCT00095875] n=NA follow-up:	induction chemotherapy comprising docetaxel, cisplatin, and fluorouracil followed by radiotherapy and carboplatin or docetaxel versus radiotherapy and cisplatin only	stage III or IV Histologically or cytologically confirmed squamous cell carcinoma of the head and neck	
<b>SWOG-S0427</b> <i>ongoing</i> [NCT00268372] n=NA follow-up:	induction chemotherapy (docetaxel,cisplatin,5FU) with or without salvage surgery followed by chemoradiotherapy (with cisplatin) versus chemoradiotherapy (with cisplatin)	Patients With Advanced Oropharyngeal Squamous Cell Cancer	
<b>XRP6976F<sub>2</sub>501</b> <i>ongoing</i> [NCT00357149] n=NA follow-up:	Neoadjuvant Docetaxel Plus Cisplatin and 5-Fluorouracil Followed by Concomitant Chemoradiotherapy versus Chemoradiotherapy Alone	Patients With Locally Advanced Squamous Cell Carcinoma of the Head and Neck	
<b>DeCIDE (IRB 13362B, Chicago)</b> <i>ongoing</i> [NCT00117572] n=NA follow-up:	Induction CT with docetaxel,cisplatin, fluorouracil followed by chemoradiotherapy (with docetaxel, fluorouracil, hydroxyurea) versus Chemoradiotherapy with docetaxel,fluorouracil, hydroxyurea	patients with nodal stage N2 or N3 head and neck cancer	Open
<b>TP vs PF</b>			
<b>Fonseca , 2005</b> n=42/41 follow-up: NA	induction CT with cisplatin/docetaxel versus induction CT with cisplatin and 5-fluorouracil (PF)	patients chemotherapy-naive with locally advanced resectable and non-resectable SCCHN	Parallel groups Open Spain
<b>TPF vs PF</b>			

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>Posner (TAX324) , 2007</b> [NCT00273546] n=255/246 follow-up: >24 months	induction chemotherapy consisting of docetaxel added to cisplatin/5-FU (TPF) followed by chemoradiotherapy versus standard cisplatin/5-FU (PF) induction chemotherapy followed by chemoradiotherapy	locally advanced (stage III/IV) squamous cell carcinoma of head and neck with unresectable tumor or candidates for organ preservation	Parallel groups open US, Canada, Argentina, Europe
<b>EORTC 24971 (TAX 323) , 2006 unpublished</b> [NCT00003888] n=177/181 follow-up: 1.75 y	induction chemotherapy with docetaxel + cisplatin + 5 FU followed by radiotherapy +/- surgery (before or after radiotherapy) versus induction chemotherapy with cisplatin + 5 FU followed by radiotherapy +/- surgery (before or after radiotherapy)	patients with stage III or IV unresectable locally advanced SCCHN	Parallel groups Open Europe
<b>GORTEC 2000-01</b> [NCT00169182] n=112/108 follow-up: NA	induction chemotherapy with docetaxel + cisplatin + 5-FU versus induction chemotherapy with cisplatin + fluorouracil	patients with locally advanced larynx and hypopharynx tumors requiring initially total laryngectomy	Parallel groups open France
<b>TAX324 (Larynx preservation subset) , 2007</b> [NCT00273546] n=90/76 follow-up: >24 months	induction chemotherapy consisting of docetaxel added to cisplatin/5-FU (TPF) followed by chemoradiotherapy , induction chemotherapy consisting of docetaxel added to cisplatin/5-FU (TPF) followed by chemoradiotherapy versus standard cisplatin/5-FU (PF) induction chemotherapy followed by chemoradiotherapy	locally advanced (stage III/IV) squamous cell carcinoma of larynx and hypopharynx, candidates for organ preservation	open US, Canada, Argentina, Europe
<b>XRP6976F/2503 ongoing</b> [NCT00261703] n=NA follow-up:	With Docetaxel-Cisplatin and 5-Fluoruracil (TPF) versus Cisplatin-5fluoruracil (PF) Followed by Concomitant Treatment With Cisplatin and Conventional Radiotherapy	Locally Advanced Squamous Cell Head and Neck Cancer, Non-Resectable	Parallel groups Open Portugal
<b>Hitt docetaxel , 2005 ongoing</b> n=NA follow-up:	induction chemotherapy with docetaxel + 5-FU+ cisplatin versus induction chemotherapy with 5-FU+ cisplatin	patients with locally advanced, unresectable SCCHN	Parallel groups open Spanish
<b>Dana-Farber Cancer Institute (Posner) import ongoing</b> [NCT00004214] n=NA follow-up:	induction CT with docetaxel, cisplatin, fluorouracil followed by chemoradiotherapy (with carboplatin) versus induction CT with cisplatin and fluorouracil followed by chemoradiotherapy (with carboplatin)	-	

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### AVENTIS-DFCI-04006, 0:

### SWOG-S0427, 0:

### XRP6976F<sub>2501</sub>, 0 :

### DeCIDE (IRB 13362B, Chicago), 0:

### Fonseca, 2005:

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Calais G, Pointreau Y, Alfonsi M, et al. Randomized phase III trial comparing induction chemotherapy using cisplatin (P) fluorouracil (F) with or without docetaxel (T) for organ preservation in hypopharynx and larynx cancer: preliminary results of GORTEC 2000-1. 42nd Annual Meeting of the American Society of Clinical Oncology; June 2-6, 2006; Atlanta, Georgia. Abstract 5506. [0]

### TAX324 (Larynx preservation subset), 2007:

### XRP6976F/2503, 0:

### Hitt docetaxel, 2005:

Hitt R, Grau JJ, Lopez-Pousa A, et al. Randomized phase II/III clinical trial of induction chemotherapy (ICT) with either cisplatin/5-fluorouracil (PF) vs docetaxel (T) plus PF (TPF) followed by chemoradiotherapy (CRT) vs CRT alone for unresectable locally advanced head and neck cancer 42nd Annual Meeting of the American Society of Clinical Oncology; June 2-6, 2006; Atlanta, Georgia. Abstract 5515 [0]

R. Hitt, J. Grau, A. Lopez-Pousa, A. Berrocal, C. Garca-Giron, J. Belon, J. Sastre, J. Martinez-Trufero, H. Cortes-Funes, J. Cruz-Hernandez Randomized phase II/III clinical trial of induction chemotherapy (ICT) with either cisplatin/5-fluorouracil (PF) or docetaxel/cisplatin/5-fluorouracil (TPF) followed by chemoradiotherapy (CRT) vs. crt alone for patients (pts) with unresectable locally advanced head and neck cancer (LAHNC). Journal of Clinical Oncology, 2006 ASCO Annual Meeting Proceedings Part I. Vol 24, No. 18S (June 20 Supplement), 2006: 5515

## 2 induction polyCT with platin

Trial	Treatments	Patients	Trials design and methods
<b>MEPFL vs no induction chemotherapy</b>			
<b>National Health Research Institutes, Taiwan</b> <i>ongoing</i> [NCT00201396] n=NA follow-up:	Induction MEPFL (Mitomycin C, Epirubicin, Cisplatin, 5-Fluorouracil, Leucovorin) three cycles followed with weekly cisplatin concurrently with radiotherapy versus Weekly cisplatin concurrently with radiotherapy	Patients with advanced nasopharyngeal Carcinoma stage IVA (T4) and/or IVB (N3) but without distant metastasis	
<b>polyCT with platin vs no induction chemotherapy</b>			
<b>Kohno , 2000</b> n=13/11 follow-up: 5.6y (5-6.6y)	induction chemotherapy with cisplatin, etoposide, mitomycin-C followed by surgery versus surgery alone	patients with previously untreated stage III and IV resectable squamous cell carcinoma of the oral cavity and pharynx	Parallel groups Open Japan
<b>Maipang (Songkla) , 1995</b> n=30/24 follow-up: NA	induction chemotherapy + surgery + post operative radiotherapy versus surgery + post operative radiotherapy	advanced stage III and IV SCCHN with resectable tumor	Parallel groups open Thailand
<b>Mazon (Crteil-82) , 1992</b> n=55/61 follow-up: NA	induction chemotherapy (bleomycin, methotrexate, 5-fluorouracil, cisplatin) + locoregional treatment (+/- surgery + radiotherapy) versus locoregional treatment alone (+/- surgery + radiotherapy )	Stage II-IV squamous cell carcinoma of the oropharynx or oral cavity	Parallel groups Open france
<b>Jaulerry Trial 2 (Curie)(HNCGIC03) , 1992</b> n=55/53 follow-up: 2.5 y (0.83-3.4y)	induction chemotherapy (cisplatin,5FU, vindesine) + radiotherapy +/- surgery versus radiotherapy	T3, T4 tumors of the oropharynx, hypopharynx, larynx, oral cavity and T2 hypopharynx	Parallel groups Open france
<b>Salvajoli (AC Camargo) , 1992</b> n=30/30 follow-up: 2.3y median	induction chemotherapy (vinblastine, mitomycin, cisplatin, bleomycin) and radiotherapy (70 Gy) versus radiotherapy alone (70 Gy)	Patients with unresectable stage IV squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx	Parallel groups open Brazil
<b>Brunin (HNCGIC02) , 1989</b> n=48/52 follow-up: 2.9y median, range 1.2-4.6	induction chemotherapy (cisplatin, bleomycin, vindesine, mitomycin) prior radiotherapy (55 Gy) +/- surgery versus radiotherapy (55 Gy) +/- surgery alone	stage III and IV carcinomas of the oral cavity, oropharynx and larynx and stage II carcinomas of the hypopharynx	Parallel groups open France

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Trial	Treatments	Patients	Trials design and methods
Schuller (SWOG 8006) , 1988 n=82/76 follow-up: median 5y	induction chemotherapy, surgery and post operative radiotherapy versus surgery and post operative radiotherapy	operable stage III-IV epidermoid carcinoma of the head and neck	Parallel groups open US
Szpirglas (Piti-81) , 1988 n=NA	-	-	
Carugati (Buenos Aires) , 1988 n=82/38 follow-up: 5 y	induction chemotherapy before radical treatment versus radical treatment	stage III and IV of SSC of the oral cavity, larynx, oropharynx	Parallel groups open Argentina
HNCP , 1987 n=140/152 follow-up: median 5.1y (range 3.1-6.6)	induction chemotherapy (cisplatin + bleomycin) + surgery + postoperative radiotherapy versus surgery + radiotherapy	resectable stage III or IV cancers of the oral cavity, larynx or hypopharynx	Parallel groups open US
<b>polyCT with platin vs cisplatin</b>			
Chauvergne , 1988 n=122/119 follow-up:	cisplatin, vincristin, methotrexate, bleomycin versus cisplatin alone	unresectable advanced squamous cell carcinoma of head and neck	Parallel groups open france

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### 3 induction polyCT without platin

Trial	Treatments	Patients	Trials design and methods
<b>polyCT without platin vs no induction chemotherapy</b>			
<b>Richard (EORTC 78-OCP) , 1991</b> n=112/110 follow-up: median 5y (range 1-9y)	intraarterial induction chemotherapy (vincristine, bleomycin) + surgery + post operative radiotherapy versus surgery + post operative radiotherapy	Squamous cell carcinoma of the oral cavity and oropharynx	Parallel groups open europe
<b>Jortay (EORTC 24771) , 1990</b> n=89/98 follow-up: 5y mean	induction chemotherapy with vincristine, bleomycin, methotrexate followed by surgery +/- radiotherapy versus surgery +/- radiotherapy	operable epidermoid carcinoma of the pyriform sinus	Parallel groups open France, Italy
<b>Holoye (MCW-1) , 1985</b> n=43/40 follow-up: at least 2y post diagnosis	induction chemotherapy (bleomycin, cytoxan, MTX, 5FU) + standard treatment (preoperative radiotherapy followed by surgery) versus standard treatment (preoperative radiotherapy followed by surgery)	Stage III and IV squamous cell carcinoma of oral cavity, oropharynx, nasopharynx, nasal cavity or paranasal sinuses, larynx hypopharynx and stage II of pyriform sinus	Parallel groups open US

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## 4 Larynx preservation

Trial	Treatments	Patients	Trials design and methods
<b>TPF vs PF</b>			
<b>Posner (TAX324) , 2007</b> [NCT00273546] n=255/246 follow-up: >24 months	induction chemotherapy consisting of docetaxel added to cisplatin/5-FU (TPF) followed by chemoradiotherapy versus standard cisplatin/5-FU (PF) induction chemotherapy followed by chemoradiotherapy	locally advanced (stage III/IV) squamous cell carcinoma of head and neck with unresectable tumor or candidates for organ preservation	Parallel groups open US, Canada, Argentina, Europe
<b>EORTC 24971 (TAX 323) , 2006 unpublished</b> [NCT00003888] n=177/181 follow-up: 1.75 y	induction chemotherapy with docetaxel + cisplatin + 5 FU followed by radiotherapy +/- surgery (before or after radiotherapy) versus induction chemotherapy with cisplatin + 5 FU followed by radiotherapy +/- surgery (before or after radiotherapy)	patients with stage III or IV unresectable locally advanced SCCHN	Parallel groups Open Europe
<b>GORTEC 2000-01</b> [NCT00169182] n=112/108 follow-up: NA	induction chemotherapy with docetaxel + cisplatin + 5-FU versus induction chemotherapy with cisplatin + fluorouracil	patients with locally advanced larynx and hypopharynx tumors requiring initially total laryngectomy	Parallel groups open France

continued...

Trial	Treatments	Patients	Trials design and methods
<b>TAX324 (Larynx preservation subset) , 2007</b> [NCT00273546] n=90/76 follow-up: >24 months	induction chemotherapy consisting of docetaxel added to cisplatin/5-FU (TPF) followed by chemoradiotherapy , induction chemotherapy consisting of docetaxel added to cisplatin/5-FU (TPF) followed by chemoradiotherapy versus standard cisplatin/5-FU (PF) induction chemotherapy followed by chemoradiotherapy	locally advanced (stage III/IV) squamous cell carcinoma of larynx and hypopharynx, candidates for organ preservation	open US, Canada, Argentina, Europe
<b>XRP6976F/2503</b> <i>ongoing</i> [NCT00261703] n=NA follow-up:	With Docetaxel-Cisplatin and 5-Fluoruracil (TPF) versus Cisplatin-5fluoruracil (PF) Followed by Concomitant Treatment With Cisplatin and Conventional Radiotherapy	Locally Advanced Squamous Cell Head and Neck Cancer, Non-Resectable	Parallel groups Open Portugal
<b>Hitt docetaxel , 2005</b> <i>ongoing</i> n=NA follow-up:	induction chemotherapy with docetaxel + 5-FU+ cisplatin versus induction chemotherapy with 5-FU+ cisplatin	patients with locally advanced, unresectable SCCHN	Parallel groups open Spanish
<b>Dana-Farber Cancer Institute (Posner) import</b> <i>ongoing</i> [NCT00004214] n=NA follow-up:	induction CT with docetaxel, cisplatin, fluorouracil followed by chemoradiotherapy (with carboplatin) versus induction CT with cisplatin and fluorouracil followed by chemoradiotherapy (with carboplatin)	-	
<b>induction PF vs surgery</b>			
<b>GETTEC , 1998</b> n=NA follow-up: median 5 y	induction chemotherapy with cisplatin and fluorouracil, followed by radiotherapy in good responders, and by total laryngectomy plus radiotherapy in poor responders versus total laryngectomy followed by radiotherapy	advanced (T3) larynx carcinoma considered for total laryngectomy	Parallel groups Open France
<b>Veterans Affairs , 1998</b> n=NA follow-up: 2.75y median (0.9-5.2)	three cycles of chemotherapy (cisplatin and fluorouracil) and definitive radiotherapy versus conventional laryngectomy and postoperative surgery	stage III and IV previously untreated carcinoma of the larynx	Parallel groups open USA

continued...



Trial	Treatments	Patients	Trials design and methods
<b>EORTC 24891 , 1996</b> [EORTC 24891] n=100/94 follow-up: 4.25 years median (0.25-8.8)	induction chemotherapy with cisplatin plus fluorouracil + radiotherapy or surgery + post operative surgery versus total laryngectomy + postoperative radiotherapy	squamous cell carcinomas of the pyriform sinus or aryepiglottic fold	Parallel groups open Europe

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Posner MR, Hershock DM, Blajman CR, Mickiewicz E, Winquist E, Gorbounova V, Tjulandin S, Shin DM, Cullen K, Ervin TJ, Murphy BA, Racz LE, Cohen RB, Spaulding M, Tishler RB, Roth B, Viroglio Rdel C, Venkatesan V, Romanov I, Agarwala S, Harter KW, Dugan M, Cisplatin and fluorouracil alone or with docetaxel in head and neck cancer. N Engl J Med 2007 Oct 25;357:1705-15 [[17960013](#)]

### EORTC 24971 (TAX 323), 2006:

Remenar E, Van Herpen C, Lluch JG, et al A randomized phase III multicenter trial of neoadjuvant docetaxel plus cisplatin and 5-fluorouracil (TPF) versus neoadjuvant PF in patients with locally advanced unresectable squamous cell carcinoma of the head and neck (SCCHN). Final analysis of EORTC 24971[Abstract] J Clin Oncol 24 (Suppl 18): A-5516, 2006

Vermorken JB, Remenar E, van Herpen C, Gorlia T, Mesia R, Degardin M, Stewart JS, Jelic S, Betka J, Preiss JH, van den Weyngaert D, Awada A, Cupissol D, Kienzer HR, Rey A, Desauois I, Bernier J, Lefebvre JL Cisplatin, fluorouracil, and docetaxel in unresectable head and neck cancer. N Engl J Med 2007;357:1695-704 [[17960012](#)]

### GORTEC 2000-01, 0:

Calais G, Pointreau Y, Alfonsi M, et al. Randomized phase III trial comparing induction chemotherapy using cisplatin (P) fluorouracil (F) with or without docetaxel (T) for organ preservation in hypopharynx and larynx cancer: preliminary results of GORTEC 2000-1. 42nd Annual Meeting of the American Society of Clinical Oncology; June 2-6, 2006; Atlanta, Georgia. Abstract 5506. [[0](#)]

### TAX324 (Larynx preservation subset), 2007:

#### XRP6976F/2503, 0:

#### Hitt docetaxel, 2005:

Hitt R, Grau JJ, Lopez-Pousa A, et al. Randomized phase II/III clinical trial of induction chemotherapy (ICT) with either cisplatin/5-fluorouracil (PF) vs docetaxel (T) plus PF (TPF) followed by chemoradiotherapy (CRT) vs CRT alone for unresectable locally advanced head and neck cancer 42nd Annual Meeting of the American Society of Clinical Oncology; June 2-6, 2006; Atlanta, Georgia. Abstract 5515 [[0](#)]

R. Hitt, J. Grau, A. Lopez-Pousa, A. Berrocal, C. Garca-Giron, J. Belon, J. Sastre, J. Martinez-Trufero, H. Corts-Funes, J. Cruz-Hernandez Randomized phase II/III clinical trial of induction chemotherapy (ICT) with either cisplatin/5-fluorouracil (PF) or docetaxel/cisplatin/5-fluorouracil (TPF) followed by chemoradiotherapy (CRT) vs. crt alone for patients (pts) with unresectable locally advanced head and neck cancer (LAHNC). Journal of Clinical Oncology, 2006 ASCO Annual Meeting Proceedings Part I. Vol 24, No. 18S (June 20 Supplement), 2006: 5515

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## 5 other induction CT

Trial	Treatments	Patients	Trials design and methods
<b>CT with methotrexate vs no induction chemotherapy</b>			
<b>Fazekas (RTOG 6801) , 1980</b> n=312/326 follow-up: 1.67y mean	induction chemotherapy with methotrexate followed by radiotherapy +/- post radiotherapy surgery versus radiotherapy alone +/- post radiotherapy surgery	locally advanced squamous cell carcinoma or lymphoepithelioma of the oral cavity, oropharynx, supraglottic larynx or hypopharynx	Parallel groups open US
<b>Richard (IGR-65) , 1974</b> n=21/18 follow-up: 5 years at least	Intra arterial infusion chemotherapy with methotrexate followed by radiotherapy versus radiotherapy alone	advanced cancer (T4) of the oral cavity and oropharynx	Parallel groups Open France
<b>PBM vs PF</b>			
<b>Clark (Dana farber cancer Institute 83-084) , 1988</b> n=55/55 follow-up:	induction chemotherapy with bleomycin, cisplatin, LTX, leucovorin (PBM) followed by local treatment (surgery and/or radiotherapy) versus induction chemotherapy with cisplatin, 5FU followed by local treatment (surgery and/or radiotherapy)	patients with previously untreated stage III and IV squamous cell carcinomas of head and neck (SCCHN)	Parallel groups open US
<b>VP16 based CT vs PF</b>			
<b>Prvost , 2005</b> n=99/98 follow-up: NA	induction chemotherapy with cisplatin+VP16 + radiotherapy versus induction chemotherapy with cisplatin+5-FU+ radiotherapy	patient with unresectable advanced head and neck cancer	Parallel groups open France

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## 6 paclitaxel based induction CT

Trial	Treatments	Patients	Trials design and methods
<b>paclitaxel based CT vs PF</b>			
<b>Hitt paclitaxel , 2005</b> n=189/193 follow-up: 1.93y (0.025-5y)	induction chemotherapy with paclitaxel, cisplatin, and fluorouracil versus induction chemotherapy with cisplatin and FU	locally advanced head and neck cancer	Parallel groups Open Spain

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## 7 PF induction CT

Trial	Treatments	Patients	Trials design and methods
<b>PF vs no induction chemotherapy</b>			
<b>Dalley (AHNTG) , 1995</b> n=140/140 follow-up: 4.8y	induction chemotherapy with cisplatin, fluorouracil followed by definitive local therapy versus definitive local therapy alone	locally advanced untreated squamous cell carcinoma of head and neck	Parallel groups open Australia

continued...

Trial	Treatments	Patients	Trials design and methods
<b>Licitra , 2003</b> [NCT00002747] n=98/97 follow-up: 6.3 y median	induction chemotherapy with cisplatin and fluorouracil followed by surgery +/- radiotherapy versus surgery alone +/- radiotherapy	resectable untreated oral cavity squamous cell carcinoma	Parallel groups Open Italy
<b>RTOG 91-11 (I+RT vs RT alone) , 2003</b> n=173/173 follow-up: 6.9y (median)	induction cisplatin plus fluorouracil followed by radiotherapy, versus radiotherapy alone	locally advanced cancer of the larynx requiring total laryngectomy	Parallel groups Open USA
<b>Hareyama , 2002</b> n=40/40 follow-up: 4.08 y (median) (range 0.3-9.2)	two courses of chemotherapy, consisting of cisplatin and 5-fluorouracil (CDDP-5FU), that were administered before radiation therapy versus radiotherapy alone	locoregional carcinoma of the nasopharynx	Parallel groups Open Japan
<b>Domenge (GETTEC) , 2000</b> n=157/161 follow-up: 5y median	induction chemotherapy with cisplatin plus fluorouracil followed by loco-regional treatment consisted either of surgery plus radiotherapy or of radiotherapy alone versus locoregional treatment consisted either of surgery plus radiotherapy or of radiotherapy alone	Patients with a squamous cell carcinoma of the oropharynx for whom curative radiotherapy or surgery was considered feasible	Parallel groups Open France
<b>Lewin (SHNG-85) , 1997</b> n=215/208 follow-up: 4.5y mean, 1.5-8y	induction chemotherapy (Cisplatin, 5 FU) followed by radiotherapy +/- surgery versus radiotherapy alone +/- surgery	Patients with non resectable squamous cell carcinoma of the oropharynx, hypopharynx and larynx, stage III to IV, or with resectable and non resectable tumor of the oral cavity stage II to IV	Parallel groups open Denmark, Norway, Sweden
<b>Gedouin (Rennes-87) , 1996</b> n=57/64 follow-up: 5y median	induction chemotherapy (cisplatin + 5FU) before regional treatment versus regional treatment alone	patients with squamous cell carcinoma of hypopharynx and base of tongue	Parallel groups open France
<b>Hasegawa (HNAP-02) , 1996</b> n=25/25 follow-up: 3.7y	2 cycles of neoadjuvant CT: CDDP (70mg/m2, day 1) and 5FU (660mg/m2, day 2-6) followed by surgery versus surgery (without preoperative treatment)	patients with resectable previously untreated advanced head and neck squamous cell carcinoma (stage III/IV M0)	
<b>Domenge (GETTEC neo1) , 1995</b> n=83/83 follow-up: median 3y	induction chemotherapy with cisplatin plus fluorouracil followed by radiotherapy versus radiotherapy	oropharyngeal tumor	Parallel groups open France

continued...

Trial	Treatments	Patients	Trials design and methods
<b>Di Blasio (Parma) , 1994</b> n=35/31 follow-up: median 4y (1.9-6.25)	induction chemotherapy with cisplatin, fluorouracil followed by locoregional treatment versus locoregional treatment alone	stage II-IV resectable head and neck cancer	Parallel groups open Italy
<b>Volling (Cologne) , 1994</b> n=48/47 follow-up: 1.75y (range 1-2y)	Induction chemotherapy (carboplatin, 5-FU) + surgery + postoperative radiotherapy versus surgery + postoperative radiotherapy	resectable stage T2-T3, N0-N2 carcinomas of oral cavity, oro- and hypopharynx and a performance status of at least 2	Parallel groups Open Deutschland
<b>Paccagnella (GSTTC-86 ) , 1994</b> n=118/119 follow-up: median 12.5 y range 10.7-14,6	four cycles of cisplatin and 5-fluorouracil followed by locoregional treatment versus locoregional treatment alone	histologically proven squamous cell carcinoma of the hypopharynx, oropharynx, oral cavity, or paranasal sinus; stage III or IV disease without distant metastases	Parallel groups open Italy
<b>Depondt (CFHNS) , 1993</b> n=NA follow-up: 2.1y	carboplatin 400mg/m2 x3, fluorouracil 5000mg/m2 x3 versus RT or S+RT	patients with head and neck cancer	Parallel groups France
<b>Tejedor (Las Palmas) , 1992</b> n=19/17 follow-up: 1y minimum	three courses of induction chemotherapy followed by radiotherapy versus radiotherapy alone	Patients with locally advanced squamous cell carcinoma of the head and neck, stages III-IV, M0	Parallel groups Open Spain
<b>Toohill (MCW-2) , 1987</b> n=27/33 follow-up: 24-44 months	induction chemotherapy (cisplatin, fluorouracil) + radiotherapy (50 Gy) + surgery versus radiotherapy (50 Gy) + surgery	advanced squamous cell carcinoma of the upper aerodigestive tract	Parallel groups Open US
<b>BNH 003 unpublished</b> n=NA follow-up: NA	cisplatin 100mg/m2 x2-3, 5 fluorouracil 4000 mg/m2 x2-3 versus surgery + radiotherapy	-	
<b>EORTC 24844 unpublished</b> [EORTC-24844] n=74/65 follow-up: NA	Induction Chemotherapy with Cisplatin and fluorouracil followed by Surgery followed by Radiotherapy versus Surgery followed by Radiotherapy	Advanced Squamous Cell Carcinoma of the Lateral Oropharynx and Lateral Posterior Oral Cavity	Parallel groups Open
<b>Hitt (PF) , 2005 ongoing</b> n=NA follow-up:	induction chemotherapy with docetaxel + 5-FU+ cisplatin , PF induction followed by chemoradiotherapy versus chemoradiotherapy	patients with locally advanced, unresectable SCCHN	open Spanish

**carboplatin, 5FU vs PF**

continued...

Trial	Treatments	Patients	Trials design and methods
<b>De Andres , 1995</b> n=46/49 follow-up: minimum 5y	induction chemotherapy with carboplatin and fluorouracil versus induction chemotherapy with cisplatin and fluorouracil	stage IV-M0 head and neck cancer	Parallel groups open Spain
<b>PF with leucovorin vs PF</b>	without leucovorin		
<b>Fonseca , 1997</b> n=18/21 follow-up: NA	induction chemotherapy with cisplatin,5FU and leucovorin versus induction chemotherapy with cisplatin and 5FU	Stage III-IVa locally advanced head and neck cancer	Parallel groups Open Spain

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