

Clinical trials of Induction chemotherapy for Head and neck cancer in article

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1 docetaxel based induction CT

| Trial | Treatments | Patients | Trials design and methods |
|--|---|---|--|
| TP vs PF | | | |
| Fonseca , 2005 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 |
| TPF vs PF | | | |
| Posner (TAX324) , 2007 [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 |
| EORTC 24971 (TAX 323) , 2006 unpublished [NCT00003888] n=177/181 follow-up: 1.75 y | induction chemotherapy with docetaxel + cisplatin + 5 FU followed by radiotherapy +/- surgery (before or after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 |
| GORTEC 2000-01 [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 |

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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

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GORTEC 2000-01, 0:

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2 PF induction CT

| Trial | Treatments | Patients | Trials design and methods |
|--|---|---|--------------------------------------|
| PF vs no induction chemotherapy | | | |
| Dalley (AHNTG) , 1995 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 |
| Licitra , 2003 [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 |
| RTOG 91-11 (I+RT vs RT alone) , 2003 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 |
| Hareyama , 2002 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 |
| Domenge (GETTEC) , 2000 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 |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|--|--|
| Lewin (SHNG-85) , 1997 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 |
| Gedouin (Rennes-87) , 1996 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 |
| Hasegawa (HNAP-02) , 1996 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) | |
| Domenge (GETTEC neo1) , 1995 n=83/83 follow-up: median 3y | induction chemotherapy with cisplatin plus fluorouracil followed by radiotherapy versus radiotherapy | oropharyngeal tumor | Parallel groups open France |
| Di Blasio (Parma) , 1994 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 |
| Volling (Cologne) , 1994 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 |
| Paccagnella (GSTTC-86) , 1994 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 |
| Depondt (CFHNS) , 1993 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 |
| Tejedor (Las Palmas) , 1992 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 |
| Toohill (MCW-2) , 1987 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 |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|--|---|--|---------------------------|
| BNH 003 <i>unpublished</i> n=NA follow-up: NA | cisplatin 100mg/m ² x2-3, 5 fluorouracil 4000 mg/m ² x2-3 versus surgery + radiotherapy | - | |
| EORTC 24844 <i>unpublished</i> [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 |

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