

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

TrialResults-center www.trialresultscenter.org

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EORTC 24971 (TAX 323) , 2006 unpublished [NCT00003888] n=177/181 follow-up: 1.75 y	induction chemotherapy with docetaxel + cisplatin + 5 FU followed by radiotherapy +/- surgery (before or after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

References

Fonseca, 2005:

Fonseca E, Grau JJ, Sastre J, Garcia-Gomez JM, Rueda A, Pastor M, Lara MA, Navalon M, Berrocal A, Tisaire JL, Cruz JJ Induction chemotherapy with cisplatin/docetaxel versus cisplatin/5-fluorouracil for locally advanced squamous cell carcinoma of the head and neck: a randomised phase II study Eur J Cancer 2005;41:1254-60 [[15908196](#)] [10.1016/j.ejca.2005.02.019](https://doi.org/10.1016/j.ejca.2005.02.019)

Posner (TAX324), 2007:

Posner MR, Herchock D, Le Lann L, Devlin PM, and Haddad RI. TAX 324: A phase III trial of TPF vs PF induction chemotherapy followed by chemoradiotherapy in locally advanced SCCHN. 42nd Annual Meeting of the American Society of Clinical Oncology; June 2-6, 2006; Atlanta

Posner MR, Herschock 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, Desautels 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]

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

References

Dalley (AHNTG), 1995:

Dalley D, Beller E, Aroney R, et al. The value of chemotherapy (CT) prior to definitive local therapy (DTL) in patients with locally advanced squamous cell carcinoma (SCC) of the head and neck (HN) Proc ASCO 1995; 14: 297

Licitra, 2003:

Licitra L, Grandi C, Guzzo M, Mariani L, Lo Vullo S, Valvo F, Quattrone P, Valagussa P, Bonadonna G, Molinari R, Cantu G Primary chemotherapy in resectable oral cavity squamous cell cancer: a randomized controlled trial. J Clin Oncol 2003;21:327-33 [[1252526](#)]

RTOG 91-11 (I+RT vs RT alone), 2003:

Forastiere AA, Goepfert H, Maor M, Pajak TF, Weber R, Morrison W, Glisson B, Trotti A, Ridge JA, Chao C, Peters G, Lee DJ, Leaf A, Ensley J, Cooper J Concurrent chemotherapy and radiotherapy for organ preservation in advanced laryngeal cancer N Engl J Med 2003;349:2091-8 [[14645636](#)] [10.1056/NEJMoa031317](#)

Forastiere AA, Mauo M, Weber RS, et al. Long-term results of Intergroup RTOG 91-11: a phase III trial to preserve the larynx: induction cisplatin/5FU and radiation therapy versus concurrent cisplatin and radiation therapy versus radiation therapy. 42nd Annual Meeting of the American Society of Clinical Oncology; June 2-6, 2006; Atlanta [0]

Hareyama, 2002:

Hareyama M, Sakata K, Shirato H, Nishioka T, Nishio M, Suzuki K, Saitoh A, Oouchi A, Fukuda S, Himi T A prospective, randomized trial comparing neoadjuvant chemotherapy with radiotherapy alone in patients with advanced nasopharyngeal carcinoma Cancer 2002;94:2217-23 [[12001120](#)] [10.1002/cncr.10473](#)

Domenge (GETTEC), 2000:

Domenge C, Hill C, Lefebvre JL, De Raucourt D, Rhein B, Wibault P, Marandas P, Coche-Dequeant B, Stromboni-Luboini M, Sancho-Garnier H, Luboini B Randomized trial of neoadjuvant chemotherapy in oropharyngeal carcinoma. French Groupe d'Etude des Tumeurs de la Tete et du Cou (GETTEC) Br J Cancer 2000;83:1594-8 [[11189100](#)] [10.1054/bjoc.2000.1512](#)

Lewin (SHNG-85), 1997:

Lewin F, Damber L, Jonsson H, et al. Neoadjuvant chemotherapy with cisplatin and 5-fluorouracil in advanced squamous cell carcinoma of the head and neck: a randomized phase III study. Int J Radiat Oncol 1997;43: 2328

Gedouin (Rennes-87), 1996:

Gedouin D, Desprez P, Perron JJ, Fleury F, Leclech G, Miglianico L, Belpomme D, Chenal C [Cancers of the base of the tongue and hypopharynx: results of a multicenter randomized trial of chemotherapy prior to locoregional treatment] Bull Cancer Radiother 1996;83:104-7 [[8688215](#)]

Hasegawa (HNAP-02), 1996:

Hasegawa Y, Matsuura H, Fukushima M, Kano M, Shimozato K. Potential suppression of distant and node metastasis by neoadjuvant chemotherapy in advanced head and neck cancer: result of a randomized trial Proc ASCO 1996; 15: 318.

Hasegawa Y et al. Proc ASCO 1994;13:286

Domenge (GETTEC neo1), 1995:

Domenge C, Lancar R, Coche-Dequean B, et al. Induction chemotherapy before radiotherapy in oropharyngeal carcinoma: a randomized trial Eur J Cancer 1995; 31A (suppl 6): S86

Di Blasio (Parma), 1994:

Di Blasio B, Barbieri W, Bozzetti A, Iotti C, Di Sarra S, Cocconi G. A prospective randomized trial in resectable head and neck carcinoma: loco-regional treatment with and without neoadjuvant chemotherapy Proc ASCO 1994; 13: 279

Volling (Cologne), 1994:

Volling P, Schröder M, Müller RP, Ebeling O, Quirin R, Stennert E. Induction chemotherapy in primary resectable head and neck tumors: a prospective randomized trial Int J Oncol 1994; 4: 90914

Volling P, Schröder M, Eckel H, Ebeling O, Stennert E [Results of a prospective randomized trial with induction chemotherapy for cancer of the oral cavity and tonsils] HNO 1999;47:899-906 [[10550374](#)]

Volling P, Schröder M [Preliminary results of a prospective randomized study of primary chemotherapy in carcinoma of the oral cavity and pharynx] HNO 1995;43:58-64 [[7713766](#)]

Paccagnella (GSTTC-86), 1994:

Paccagnella A, Orlando A, Marchiori C, Zorat PL, Cavaniglia G, Sileni VC, Jirillo A, Tomio L, Fila G, Fede A Phase III trial of initial chemotherapy in stage III or IV head and neck cancers: a study by the Gruppo di Studio sui Tumori della Testa e del Collo J Natl Cancer Inst 1994;86:265-72 [[8158680](#)]

Zorat PL, Paccagnella A, Cavaniglia G, Loreggian L, Gava A, Mione CA, Boldrin F, Marchiori C, Lunghi F, Fede A, Bordin A, Da Mosto MC, Sileni VC, Orlando A, Jirillo A, Tomio L, Pappagallo GL, Ghi MG Randomized phase III trial of neoadjuvant chemotherapy in head and neck cancer: 10-year follow-up J Natl Cancer Inst 2004;96:1714-7 [[15547184](#)] [10.1093/jnci/djh306](#)

Depondt (CFHNS), 1993:

Depondt J, Gehanno P, Martin M, Lelievre G, Guerrier B, Peytral C, Schott H, Pellae-Cosset B Neoadjuvant chemotherapy with carboplatin/5-fluorouracil in head and neck cancer Oncology 1993;50 Suppl 2:23-7 [[8233298](#)]

Tejedor (Las Palmas), 1992:

Tejedor M, Murias A, Soria P, Aguiar J, Salinas J, Hernandez MA, Molano F, Gonzalez G Induction chemotherapy with carboplatin and fluorouracil in advanced head and neck cancer. A randomized study Am J Clin Oncol 1992;15:417-21 [[1524042](#)]

Toohill (MCW-2), 1987:

Toohill RJ, Anderson T, Byhardt RW, Cox JD, Duncavage JA, Grossman TW, Haas CD, Haas JS, Hartz AJ, Libnoch JA Cisplatin and fluorouracil as neoadjuvant therapy in head and neck cancer. A preliminary report Arch Otolaryngol Head Neck Surg 1987;113:758-61 [[3580158](#)]

BNH 003, 0:

Pignon JP, Bourhis J, Domenge C, Designe L Chemotherapy added to locoregional treatment for head and neck squamous-cell carcinoma: three meta-analyses of updated individual data. MACH-NC Collaborative Group. Meta-Analysis of Chemotherapy on Head and Neck Cancer Lancet 2000;355:949-55 [[10768432](#)]

EORTC 24844, 0:

Pignon JP, Bourhis J, Domenge C, Designe L Chemotherapy added to locoregional treatment for head and neck squamous-cell carcinoma: three meta-analyses of updated individual data. MACH-NC Collaborative Group. Meta-Analysis of Chemotherapy on Head and Neck Cancer Lancet 2000;355:949-55 [[10768432](#)]

3 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

TrialResults-center is non-profit and self-funded.