PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

A Randomized Phase III Multicenter Trial of Neoadjuvant Docetaxel (Taxotere) Plus Cisplatin Plus 5-Fluorouracil Versus Neoadjuvant Cisplatin Plus 5-Fluorouracil in Patients With Locally Advanced Inoperable Squamous Cell Carcinoma of the Head and Neck

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Radiation therapy uses high-energy x-rays to damage tumor cells. Combining more than one drug and combining chemotherapy with radiation therapy may kill more tumor cells. It is not yet known which regimen of combination chemotherapy is more effective for advanced head and neck cancer.

PURPOSE: Randomized phase III trial to compare the effectiveness of two regimens of combination chemotherapy plus radiation therapy in treating patients who have advanced head and neck cancer.

Brief Summary in Scientific Language

OBJECTIVES: I. Compare the progression free survival of patients with locally advanced, inoperable squamous cell carcinoma of the head and neck treated with cisplatin plus fluorouracil with or without docetaxel as a neoadjuvant to radiotherapy. II. Compare the response rate, response duration, toxicity, local symptoms, and time to disease progression of these treatment regimens in this patient population. III. Evaluate the quality of life in

these patients.

OUTLINE: This is a randomized, multicenter study. Patients are stratified according to primary tumor site (oral cavity vs oropharynx vs hypopharynx vs larynx) and institution.

Patients are randomized to one of two treatment arms. Arm I: Patients receive docetaxel IV over 1 hour, immediately followed by cisplatin IV over 1 hour on day 1 and fluorouracil (5-FU) IV as a continuous infusion on days 1-5. Arm II: Patients receive cisplatin IV over 1 hour on day 1 followed by 5-FU IV as a continuous infusion on days 1-5. Treatment continues every 3 weeks for 4 courses in the absence of disease progression or unacceptable toxicity.

Patients receive radiotherapy following chemotherapy within 3-6 weeks of last course.

Radiotherapy is administered 5 days a week for up to 7 weeks. Quality of life is assessed before treatment, at courses 2 and 4, and at 6 and 9 months. Patients are followed every 3 months for the first 2 years and then every 6 months until death.

PROJECTED ACCRUAL: A total of 348 patients will be accrued for this study within 24 months.

Organizational Data

- DRKS-ID: **DRKS00005527**
- Date of Registration in DRKS: **2014/02/18**
- Date of Registration in Partner Registry or other Primary Registry: **1999/11/01**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT00003888 (ClinicalTrials.gov)**
- Sponsor-ID: **EORTC-24971 (European Organisation for Research and Treatment of Cancer - EORTC)**
- Other Secondary-ID: **RP-56976-V-323**

Health condition or Problem studied

- Free text: **Head and Neck Cancer**
- ICD10: **C01 - Malignant neoplasm of base of tongue**

ICD10: **C01 - Malignant neoplasm of base of tongue**

- ICD10: **C02 - Malignant neoplasm of other and unspecified parts of tongue**
- ICD10: **C03 - Malignant neoplasm of gum**
- ICD10: **C04 - Malignant neoplasm of floor of mouth**
- ICD10: **C05 - Malignant neoplasm of palate**
- ICD10: **C06 - Malignant neoplasm of other and unspecified parts of mouth**
- ICD10: **C10 - Malignant neoplasm of oropharynx**
- ICD10: **C13 - Malignant neoplasm of hypopharynx**
- ICD10: **C32 - Malignant neoplasm of larynx**

Interventions/Observational Groups

- Arm 1: **Drug: cisplatin**
- Arm 2: **Drug: docetaxel**
- Arm 3: **Drug: fluorouracil**
- Arm 4: **Radiation: radiation therapy**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **[---]***
- Purpose: **Treatment**
- Assignment: **[---]***
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

[---]*

Secondary Outcome

[---]*

Countries of recruitment

- AT **Austria**
- BE **Belgium**
- [---]* **[---]***
- FR **France**
- DE **Germany**
- GR **Greece**
- HU **Hungary**
- IT **Italy**
- NL **Netherlands**
- PL **Poland**
- SK **Slovakia**
- ES **Spain**
- CH **Switzerland**
- TR **Turkey**
- UK **United Kingdom**

Locations of Recruitment

- **Martin Luther Universitaet, Halle**
- **Caritasklinik St. Theresia, Saarbrucken**
- **Mutterhaus der Borromaerinnen, Trier**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **1999/04/30**
- Target Sample Size: **359**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**

Gender: **Both, male and female**

Minimum Age: **18 Years**

- Maximum Age: **70 Years**

Additional Inclusion Criteria

DISEASE CHARACTERISTICS: Histologically or cytologically proven locally advanced squamous cell carcinoma of the head and neck Stage III or IV without distant metastases Unresectable Primary tumor sites: Oral cavity Oropharynx Hypopharynx Larynx Must have at least one measurable lesion

PATIENT CHARACTERISTICS: Age: 18 to 70 Performance status: WHO 0-1 Life expectancy: Not specified Hematopoietic: Absolute neutrophil count at least 2,000/mm3 Platelet count at least 100,000/mm3 Hemoglobin at least 10 g/dL Hepatic: Bilirubin no greater than upper limit of normal (ULN) SGOT and SGPT no greater than 2.5 times ULN Alkaline phosphatase no greater than 5 times ULN No SGOT and SGPT greater than 1.5 times ULN AND alkaline phosphatase greater than 2.5 times ULN Renal: Creatinine no greater than 1.4 mg/dL OR Creatinine clearance at least 60 mL/min Cardiovascular: At least 6 months since prior myocardial infarction No unstable, treated cardiac disease Pulmonary: At least one year since prior hospitalization for chronic obstructive pulmonary disease Neurologic: No neurologic or psychiatric disorders (e.g., dementia or seizures) No concurrent peripheral neuropathy greater than grade 1 Other: No active uncontrolled infection No active peptic ulcer No alteration in hearing At least 5 years since any other neoplastic disease except curatively treated basal or squamous cell skin cancer, carcinoma in situ of the cervix, or other cancer curatively treated by surgery Not pregnant or nursing Fertile patients must use effective contraception No other psychological, familial, sociological, or geographical condition that would prevent compliance

PRIOR CONCURRENT THERAPY: Biologic therapy: No primary prophylactic colony stimulating factors during the first course of therapy Chemotherapy: No prior or concurrent chemotherapy Endocrine therapy: At least 3 weeks since prior corticosteroid No chronic corticosteroid therapy (greater than 3 months) Radiotherapy: No prior radiotherapy

Surgery: No prior surgery for this cancer Other: At least 30 days since prior treatment in a clinical trial No concurrent use of drugs that interact with fluorouracil (e.g., cimetidine, allopurinol, folic acid or leucovorin calcium) No other concurrent investigational drugs or anticancer treatment

Exclusion criteria

[---]*

Addresses

- **Primary Sponsor**

  European Organisation for Research and Treatment of Cancer - EORTC

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

- **Contact for Scientific Queries**

  Universitair Ziekenhuis Antwerpen
  Jan B. Vermorken, MD, PhD

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

- **Contact for Public Queries**

  Universitair Ziekenhuis Antwerpen
  Jan B. Vermorken, MD, PhD

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

Sources of Monetary or Material Support

- **[---]***

  Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

[---]*

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Further trial documents **Clinical trial summary from the National Cancer Institute's PDQ® database**
- Further trial documents **Jansen J, Vermorken JB, Boote D, et al.: Cost-effectiveness analysis of the EORTC 24971 (TAX 323) trial comparing docetaxel plus cisplatin and 5-fluorouracil versus standard treatment (cisplatin and 5-fluorouracil) as induction chemotherapy followed by radiation therapy in locally advanced unresectable squamous cell carcinoma of the head and neck (SCCHN). [Abstract] J Clin Oncol 25 (Suppl 18): A-6090, 321s, 2007.**
- Trial results **van Herpen CM, Mauer ME, Mesia R, Degardin M, Jelic S, Coens C, Betka J, Bernier J, Remenar E, Stewart JS, Preiss JH, van den Weyngaert D, Bottomley A, Vermorken JB. Short-term health-related quality of life and symptom control with docetaxel, cisplatin, 5-fluorouracil and cisplatin (TPF), 5-fluorouracil (PF) for induction in unresectable locoregionally advanced head and neck cancer patients (EORTC 24971/TAX 323). Br J Cancer. 2010 Sep 14; [Epub ahead of print]; 20842129**
- Trial results **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, Desaunois I, Bernier J, Lefebvre JL; EORTC 24971/TAX 323 Study Group. Cisplatin, fluorouracil, and docetaxel in unresectable head and neck cancer. N Engl J Med. 2007 Oct 25;357(17):1695-704.; 17960012**
- Trial results **Bernier J, Coens C, Remenar E, et al.: Impact on quality of life (QoL) of the addition of docetaxel (T) to neoadjuvant cisplatin plus 5-fluorouracil treatment in patients with locally advanced unresectable squamous cell carcinoma of the head and neck (SCCHN): EORTC study 24971. [Abstract] J Clin Oncol 24 (Suppl 18): A-5522, 285s, 2006.**
- Trial results **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.**
- Trial results **Vermorken JB, Remenar E, Van Herpen C, et al.: Standard cisplatin/infusional 5-fluorouracil (PF) vs docetaxel (T) plus PF (TPF) as neoadjuvant chemotherapy for nonresectable locally advanced squamous cell carcinoma of the head and neck (LA-SCCHN): a phase III trial of the EORTC Head and Neck Cancer Group (EORTC #24971). [Abstract] J Clin Oncol 22 (Suppl 14): A-**

5508, 490s, 2004.