

# Phase III trial of gemcitabine concurrent with radiation for locally advanced squamous cell carcinoma of the head and neck

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|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>06/08/2007   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>27/09/2007 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>27/09/2007       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
007/022/OMI

## Study information

**Scientific Title**

**Study objectives**

Cisplatin concurrent with radiation therapy has been used in stage IV head and neck cancer. One previous study has reported that the combination of low-doses of gemcitabine with radiotherapy has a similar response in terms of overall survival and progression-free survival to that of cisplatin concurrent with radiation in patients with III, IVa, IVb stage disease. Based on these facts we decided to perform a randomised phase III trial to compare cisplatin concurrent with radiation versus low-dose gemcitabine concurrent with radiation for locally advanced squamous cell carcinoma of the head and neck. The hypothesis being a similar response in both conditions, but better control of adverse effects with low-dose gemcitabine/radiotherapy.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics approval received from the National Cancer Institute of Mexico Ethics and Scientific Committee (Comite de Etica y Científico del Instituto Nacional de Cancerologia) on the 5th March 2007 (ref: CB/341/06).

### **Primary study design**

Interventional

### **Study design**

Randomised controlled trial

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Advanced squamous cell carcinoma of the head and neck

### **Interventions**

Patients with squamous cell carcinoma of the head and neck staged IVb will be randomised to either:

Arm 1: cisplatin at 50 mg/m<sup>2</sup>, administered intravenously over 60 minutes with 125 ml mannitol once weekly, 3 hours before radiation. The total dose of radiation will be administered to the macroscopic tumour and to potential sites of microscopic spread was 70 Gy, over 7 weeks.

Arm 2: gemcitabine at 100 mg/dl, administered intravenously over 30 minutes once weekly, 3 hours before radiation. The total dose of radiation will be administered to the macroscopic tumour and to potential sites of microscopic spread was 70 Gy, over 7 weeks.

The maximal dose to the spinal cord was restricted to 45 and 54 Gy to the brain stem and optic nerves, respectively. Total treatment time is seven weeks; overall time of this trial is three years.

### **Intervention Type**

Drug

### **Phase**

Phase III

### **Drug/device/biological/vaccine name(s)**

Gemcitabine, cisplatin, mannitol

**Primary outcome(s)**

Data of interest (haematologic toxicity, presence of mucositis, skin rash, nausea/vomiting, dysphagia, odynophagia, etc) is assessed and collected at the time of each visit. The first timepoint at which the outcomes will be measured will be at 6 months after inclusion in the study. Toxicity is evaluated according to the National Cancer Institute - Common Toxicity Criteria version 3 (NCI-CTC v.3.0).

**Key secondary outcome(s)**

Efficacy in terms of overall and progression free-survival, will be determined with clinical examination, Computed Tomography (CT)-scans, medical lab tests (metabolic profile, Complete Blood Count [CBC], blood chemistry), endoscopy and biopsy studies.

**Completion date**

31/12/2010

**Eligibility****Key inclusion criteria**

1. International Union Against Cancer (UICC) classification stage IVb
2. Histologically proven and measurable squamous cell carcinoma of the head and neck (oral cavity, oropharynx, larynx, hypopharynx)
3. Previously untreated
4. Unresectable disease (when surgical resection was considered technically not feasible or surgical resection with clear margins was estimated to produce significant organ and/or function loss) or refused surgery
5. Aged 18 to 70 years
6. Squamous cell carcinoma of the head and neck without distant metastases
7. Karnofsky performance status score greater than or equal to 70%
8. Normal renal, hepatic and haematological function
9. Negative pregnancy
10. Informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Not Specified

**Key exclusion criteria**

1. Surgery and chemotherapy previously
2. Previous malignancy except non-melanoma skin cancer and cervical carcinoma in situ
3. Any clinical manifestation of distant metastases
4. Therapy concurrent 30 days previous with other experimental anti-neoplastic treatment
5. Systemic and/or uncontrolled disease that precludes the use of chemotherapy
6. Hypersensitivity to gemcitabine or cisplatin

**Date of first enrolment**

01/06/2007

**Date of final enrolment**

31/12/2010

## Locations

**Countries of recruitment**

Mexico

**Study participating centre**

St. Fernando Avenue No. 22

Mexico City

Mexico

14080

## Sponsor information

**Organisation**

National Cancer Institute of Mexico (Instituto Nacional de Cancerologia [INCAN]) (Mexico)

**ROR**

<https://ror.org/04z3afh10>

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

National Cancer Institute of Mexico (Instituto Nacional de Cancerologia [INCAN]) (Mexico)

# Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration