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

Submission date 06/08/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 27/09/2007	**Overall study status** Completed	
Last Edited 27/09/2007	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jose Luis Aguilar Ponce

Contact details
St. Fernando Avenue No. 22
Sec. XVI
Mexico City
Mexico
14080

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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^2, 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 measure
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).

Secondary outcome measures
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.

Overall study start date
01/06/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
216

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. Hypersensibility 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)

Sponsor details
c/o Dr Jose Luis Aguilar Ponce
St. Fernando Avenue No. 22
Sec. XVI
Mexico, D.F.
Mexico City
Mexico
14080

Sponsor type
Research organisation

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration