

Outpatient chemotherapy protocol using 3 consolidated drugs (cisplatin, 5 fluoururacil and leucovorin) in a different scheme for the treatment of head and neck and oesophageal cancer, designed for patients without surgical and radiation therapy options

Submission date 18/01/2008	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 26/02/2008	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 26/02/2008	Condition category Cancer	☐ Individual participant data
		☐ 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

Study information

Scientific Title

Low cost, outpatient, cisplatin, 5-fluorouracil and leucovorin chemotherapy regimen for advanced head and neck, and upper oesophageal carcinomas

Study objectives

Evaluate the combination of bolus CDDP cisplatin, 5-fluorouracil and leucovorin (CFL) in patients with advanced (residual, metastatic or recurrent) squamous cell carcinoma (SCC) of head (H)/neck (N) and oesophagus (E), aiming at a feasible and low cost chemotherapy (CHT) regimen to circumvent the need of infusion pumps and/or hospital admission.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the ABC Medical School Ethics Committee in December 2004 (ref: 185/2004).

Primary study design

Interventional

Study design

Phase II, single arm study conducted at a single Brazilian Institution

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Head and Neck and Upper oesophageal carcinoma

Interventions

Chemotherapy as follows:

Leucovorin 20 mg/m²/day bolus infusion for four days (D1 - D4), followed by 5-fluorouracil 370 mg/m²/day bolus infusion for four days (D1 - D4), and Cisplatin 25 mg/m²/day in 90 minutes infusion for three days (D1 - D3), every 21 to 28 days, depending upon hematological recovery.

Follow up is until patient death, expected to be less than 24 months for each patient.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

CDDP cisplatin, 5-fluorouracil and leucovorin (CFL)

Primary outcome(s)

1. Quality of life (QoL) evaluated using European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer patients (EORTC QLQ-C30) questionnaire, previously used in Portuguese, at the beginning of study and before each cycle
2. Toxicities analysed according to National Cancer Institute (NCI) criteria before each cycle

together with KPS, clinical reassessment and laboratory evaluation

3. Response, evaluated by computed tomography (CT) scans after 3rd and 6th cycles of chemotherapy and analysed by response evaluation criteria in solid tumours (RECIST)
4. Performance status by measured with Karnofsky Performance Status (KPS)

Key secondary outcome(s)

1. Overall survival - time between enrolment and death
2. Progression Free Survival - time between enrolment and disease progression

Completion date

01/02/2008

Eligibility

Key inclusion criteria

1. Advanced or recurrent, histologically confirmed, head and neck and oesophagus squamous cell carcinoma
2. Patients have to be 18 years of age or older, either sex
3. Normal renal function
4. Measurable disease by the response evaluation criteria in solid tumours (RECIST)
5. Karnofsky performance status (KPS) equal or greater to 50%

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Not meeting the inclusion criteria
2. Concomitant radiation therapy
3. Not a candidate for chemotherapy

Date of first enrolment

01/01/2005

Date of final enrolment

01/02/2008

Locations

Countries of recruitment

Brazil

Study participating centre

Rua Mere Amedea 833

Sao Paulo

Brazil

02125-001

Sponsor information

Organisation

Hospital Mario Covas (Brazil)

ROR

<https://ror.org/00s7ek396>

Funder(s)

Funder type

Research organisation

Funder Name

ABC Foundation (Brazil)

Funder Name

Hospital Mario Covas (Brazil)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration