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Outpatient chemotherapy protocol using 3 cosolidated 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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 26/02/2008	**Overall study status** Completed	
Last Edited 26/02/2008	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Vanessa Fabricio

Contact details
Rua Mere Amedea 833
Sao Paulo
Brazil
02125-001
vcf35@terra.com.br

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Low cost, outpatient, cisplatinum, 5-fluoururacil and leucovorin chemotherapy regimen for advanced head and neck, and upper oesophageal carcinomas

Study objectives
Evaluate the combination of bolus CDDP cisplatinum, 5-fluoururacil 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).

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

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Head and Neck and Upper oesophageal carcinoma

Interventions
Chemotherapy as follows:
Leucovorin 20 mg/m^2/day bolus infusion for four days (D1 - D4), followed by 5-fluoururacil 370 mg/m^2/day bolus infusion for four days (D1 - D4), and Cisplatinum 25 mg/m^2/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 then 24 months for each patient.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
CDDP cisplatinum, 5-fluoururacil and leucovorin (CFL)

Primary outcome measure
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)

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

Overall study start date
01/01/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
15 patients

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)

Sponsor details
Rua Henrique Calderazzo, 321
Bairro Paraíso
Santo Andre
Brazil
09190-615
sau@hesa-fuabc.org.br

Sponsor type
Hospital/treatment centre

Website

http://www.hospitalmariocovas.org.br

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

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