ISRCTN08658578 https://doi.org/10.1186/ISRCTN08658578

Comparative study of two different induction chemotherapy regimens in head and neck cancer

Submission date 26/12/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 18/02/2010	**Overall study status** Completed	
Last Edited 18/02/2010	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Phase II randomised study comparing Docetaxel, Cisplatin, 5-FU (DCF) with Cisplatin, 5-FU(CF) as induction chemotherapy in head and neck cancer

Acronym
GORGANI IV

Study objectives
Response rate using DCF is better than CF.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by local medical ethics committee at the Shahid Beheshti University of Medical Sciences on the 10th of September 2009 (ref: 1001)

Study design
Phase II single centre randomised parallel group prospective clinical 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
Locally advanced head and neck cancer

Interventions
Eligible patients will be randomised to receive CF or DCF.
Patients in CF arm will receive cisplatine 75 mg/m2 on day 1 and 5Fu 750 mg/m2 on day 1 to 5 of each cycle.
Patients in DCF group will receive docetaxel 75 mg/m2 additional to above drugs on day 2 of each cycle.
Patients will receive two cycles.
After two cycles, responding patients and no-responding patients who are not candidates for surgery will be treated using chemoradiation according to the physician's opinion.
All patients will be followed every 3 to 8 week for 1 year and then every 4 to 6 month until death or recurrence.

Randomisation stratified according to PS, age (<50,>50)

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Docetaxel, cisplatin, fluorouracil (5-FU) (DCF) and cisplatin, 5-FU (CF)

Primary outcome measure
Response will be evaluated at day 21 of second cycle using Response Evaluation Criteria in Solid Tumours (RECIST) criteria and computed topography (CT).

Secondary outcome measures
Toxicity will be evaluated at day 21 of each cycle and the most serious adverse effect according to WHO criteria during the cycle will be recorded.

Overall study start date
10/07/2009

Completion date
10/12/2010

Eligibility

Key inclusion criteria
1. Histological proven head and neck squamous cell carcinoma other than salivary gland tumour and sinonasal carcinoma
2. Measurable primary tumour or lymph node or both
3. T3 or T4 N0, T1-T4 N2-3
4. Age from 16 till 70 years
5. Performance status ≤2 according to ECOG classification
6. No previous chemotherapy is allowed
7. Adequate bone marrow, hepatic & renal functions
7.1. Haemoglobin ≥ 11 g/dl,
7.2. Platelets ≥ 100000 / mm3
7.3. Absolute Neutrophil Count ≥ 1500/mm3
7.4. Bilirubin = Normal Value
7.5. Transaminases = Normal Value
7.6. Creatinine ≤ 1 mg/dl
8. Absence of neuropathy
9. Absence of active co-morbid illness (uncontrolled infection, cardiopulmonary disease)
10. Complete initial work up within 2 weeks prior to first chemotherapy infusion

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Any metastasis
2. Pregnant or lactating women.
3. Other serious illness or medical conditions.
4. Any chemotherapy administered before entering study
5. Any patient with early stage cancer who can be treated without mutilating surgery
6. Any contraindication for one of the drugs in chemotherapeutic regimens or radiotherapy

Date of first enrolment
10/07/2009

Date of final enrolment
10/12/2010

Locations

Countries of recruitment
Iran

Study participating centre
Imam Hossein Hospital,
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Sponsor information

Organisation
Shahid Beheshti University of Medical Sciences (Iran)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/034m2b326

Funder(s)

Funder type
University/education

Funder Name
Shahid Beheshti University of Medical Sciences (Iran)

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