

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

Submission date 26/12/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 18/02/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/02/2010	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<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

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

Study type(s)

Treatment

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 cisplatin 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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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,

Tehran

Iran

1617763141

Sponsor information

Organisation

Shahid Beheshti University of Medical Sciences (Iran)

ROR

<https://ror.org/034m2b326>

Funder(s)

Funder type

University/education

Funder Name

Shahid Beheshti University of Medical Sciences (Iran)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration