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Efficacy and toxicity of concomitant chemoradiation with weekly gemcitabine /cisplatin in comparison with weekly cisplatin in cervical cancer: a phase II, randomised trial

Submission date 23/05/2007	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 14/11/2007	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 05/12/2008	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
691

Study information

Scientific Title

Acronym
Gorgani 1

Study objectives
Chemoradiation with weekly cisplatin and gemcitabine prolong disease free survival in cervical cancer compared with chemoradiation with weekly cisplatin.

Please note that as of 05/12/2008 this record was updated to reflect that this trial was stopped in January 2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Shaheed Beheshti University of Medical Science (SBMU) Ethics Committee (ref: 691).

Study design
Phase II, randomised 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
Cervical cancer (FIGO stage IB, II , III, IVA)

Interventions
Initial workup:
1. Complete physical examination
2. Pelvic examination without anaesthesia by at least two gynaecologists/oncologists
3. Chest X ray

4. Abdomino-pelvic spiral multi-detector Computed Tomograpy (CT) scan with Intravenous (IV) contrast
5. Sigmoidoscopy and colonoscopy if required
6. Complete blood cell counts with platelets, blood urea, serum creatinine, liver enzymes, and urine analysis

Treatment:
1. Radiation therapy:
1.1. Whole pelvic External Beam Radiation Therapy (EBRT) 4500 - 5040 cGy in 25 - 28 fractions with cobalt 60 teletherapy 5 fractions a week. Duration of treatment: 5 to 5.5 weeks.
1.2. Intracavitary brachytherapy (ICRT) with Ce137 2500 - 3000 cGy to point A, 1 to 2 weeks after completion of whole pelvic irradiation. ICRT will be carried out 1-2 week after the end of EBRT.

2. Chemotherapy:
All chemotherapy will be administered weekly during EBRT and ICRT. Anti-emetic drug will be used as per department protocol. Transfusion will be allowed for Hb less than 12 g/dl at start of treatment or any time during therapy to correct it to 12 g/dl.
2.1. Arm A: Following hydration with 1000 ml of normal saline (n/s) for 1 hour, cisplatin 40 mg /m^2 in 500 ml n/s plus 50 ml manitol 20% will be infused for 40 minutes, followed by 500 ml of n /s for 30 minutes
2.2. Arm B: Gemcitabine 100 mg/m^2 in 200 ml n/s for 30 minutes will be added to Arm A chemotherapy

If Absolute Neutrophile Count (ANC) is less than 100 x 10^6/L and/or platelet count less than 100 x 10^9/L chemotherapy will be postponed. Dose modification will not be allowed for any of the drugs. Radiotherapy will be postponed if any Grade 3 or 4 hematological toxicity or diarrhoea occur. Treatment will be resumed when toxicity Grade returns to 1.

Duration of the entire course of treatment: Less than 10 weeks

Periodic evaluation:
1. Complete blood cell counts, blood urea, serum creatinine, and liver enzymes will be checked weekly during treatment on the day of chemotherapy, and every month after treatment for 3 month then every 3 month for 1 year and every 6 month thereafter
2. Pelvic examination without anaesthesia, 40 to 45 days after completion of chemoradiation and then at each visit
3. Chest X ray and abdomino-pelvic CT scan with IV contrast, 40 to 45 days after completion of chemoradiation and then if required

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Gemcitabine, cisplatin

Primary outcome measure
Two year disease free survival (time from completion of chemoradiation to first pathologically documented local recurrence or distant metastasis out of pelvis).

Secondary outcome measures
The following will be assessed at the end of patient accrual:
1. Clinical complete response rate (complete disappearance of tumor radiologically and clinically in the first evaluation after treatment)
2. Toxicity profile according to the World Health Organization (WHO) criteria
3. Overall survival (time from completion of chemoradiation to death)

Overall study start date
22/11/2006

Completion date
22/11/2008

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Women with untreated locally advanced cervical cancer International Federation of Gynaecology and Obstetrics (FIGO) stage IB, II, III, IVA
2. Histologically confirmed Squamous Cell Carcinoma (SCC)
3. Aged between 18 - 70 years
4. Performance status less than or equal to 2 in Eastern Cooperative Oncology Group (ECOG) scale
5. No active co-morbid illness (uncontrolled infection, cardiopulmonary disease, uncontrolled diabetes mellitus)
6. Laboratory data at start of chemotherapy:
6.1. Haemoglobin (Hb) 12 g/dl or corrected to 11 g/dl before the start of therapy
6.2. Platelets (Plt) 100 x 10^9/L
6.3. Absolute Neutrophil Count (ANC) more than or equal to 1.5 x 10^9/L
6.4. Creatinine (Cr) less than or equal to 1.5 x Upper Limit of Normal (ULN)
6.5. Billirubin less than or equal to 1.5 ULN
6.6. Aspartate Aminotransferase (AST) less than or equal to 2 x ULN
6.7. Alanine Aminotransferase (ALT) less than or equal to 2 x ULN

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
80 (40 in each group)

Key exclusion criteria
1. Any metastatic disease
2. Previous pelvic irradiation
3. History of other malignancy except non-melanoma skin cancer
4. Disease out of the pelvis and para-aortic lymph nodes

Date of first enrolment
22/11/2006

Date of final enrolment
22/11/2008

Locations

Countries of recruitment
Iran

Study participating centre
Department of Radiation Oncology
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Funder type
University/education

Funder Name
Shaheed Beheshti University of Medical Science (SBMU) (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