

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/11/2007	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/12/2008	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

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 Tomography (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 Ce^{137} 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/m² 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/m² in 200 ml n/s for 30 minutes will be added to Arm A chemotherapy

If Absolute Neutrophil Count (ANC) is less than $100 \times 10^6/\text{L}$ and/or platelet count less than $100 \times 10^9/\text{L}$ 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 months then every 3 months for 1 year and every 6 months 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) $100 \times 10^9/L$
 - 6.3. Absolute Neutrophil Count (ANC) more than or equal to $1.5 \times 10^9/L$
 - 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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Sponsor information**Organisation**

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Funder(s)

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