

Weekly neoadjuvant chemotherapy followed by radical chemoradiation for locally advanced cervical cancer

Submission date 29/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 10/09/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-chemotherapy-followed-by-chemotherapy-and-radiotherapy-together-for-locally-advanced-cervical-cancer>

Contact information

Type(s)

Scientific

Contact name

Ms Mandy Feeney

Contact details

Cancer Research UK and UCL Cancer Trials Centre
90 Tottenham Court Road
London
United Kingdom
W1T 4TJ

Additional identifiers

Clinical Trials Information System (CTIS)

2005-000134-20

ClinicalTrials.gov (NCT)

NCT00462397

Protocol serial number

1517

Study information

Scientific Title

Phase II non-randomised interventional treatment study of weekly neoadjuvant chemotherapy followed by radical chemoradiation for locally advanced cervical cancer

Acronym

CxII

Study objectives

For the past 10 years cisplatin-based chemoradiation (CRT) has been the treatment of choice for all patients with locally advanced cervical cancer. The key CRT trials showed a reduction in the risk of death by 30 - 50% with an absolute improvement in 5 year survival of 12%. However, a large proportion of patients in these trials had early stage disease (stage I, II) so the results may not be broadly applicable to women with more advanced disease/large tumours, or positive nodes. The outlook for such patients remains poor and new approaches are needed.

To date, trials addressing the role of neoadjuvant chemotherapy (NACT) have generated conflicting data. Although a meta-analysis of 21 randomised trials failed to show any overall improvement in survival with NACT, an association between outcome and cycle length has been observed. Trials with a cycle length of 14 days or less were associated with an improvement in survival of approximately 7% at 5 years, while longer cycle lengths had a detrimental effect on outcome.

Therefore, it is postulated that a short course of dose dense NACT with weekly cycles of treatment prior to definitive CRT might downstage the tumours, lengthen the exposure to systemic treatment and improve outcome. Several cytotoxic agents have shown activity in cervical cancer, however very few of these agents have been tested in the weekly setting. This phase II study will assess the use of neoadjuvant weekly paclitaxel and carboplatin chemotherapy followed by concomitant chemoradiation in 50 patients with locally advanced cervical cancer.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cambridgeshire 1 Research Ethics Committee approved on the 17/05/2005 (ref: 04/Q0104/163)

Study design

Non-randomised interventional treatment trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: National Cancer Research Network; Subtopic: Gynaecological Cancer; Disease: Cervix

Interventions

Neoadjuvant chemotherapy:

Weekly treatment for six weeks: paclitaxel (80 mg/m² IV) followed by carboplatin AUC2 IV on days 1, 8, 15, 22, 29 and 36.

Chemoradiation:

Cisplatin: 40 mg/m² (maximum 70 mg) weekly for 6 weeks maximum, commencing in week 7 of treatment regimen (or as soon as blood counts have recovered).

Pelvic radiotherapy: 50.4 Gy in 28# over 5.5 weeks

High dose rate brachytherapy: 14 Gy in 2# (1 or 2 intracavitary insertions)

Pelvic sidewall boost (unilateral or bilateral) for all patients FIGO stage IIb and above with parametrial/pelvic sidewall disease extension, 5.4 Gy in 3# over 3 days.

Patient follow-up after treatment: 3 monthly for 2 years

Study entry: registration only

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Cisplatin

Primary outcome(s)

Overall response to both the neoadjuvant combination chemotherapy and the concomitant chemoradiotherapy. 6 week assessment after neoadjuvant chemotherapy by clinical examination and MRI pelvis according to RECIST; 12 week assessment after concomitant chemoradiotherapy by clinical examination, MRI pelvis and CT abdomen by RECIST.

Key secondary outcome(s)

1. Response rate to neoadjuvant chemotherapy
2. The toxicity of neoadjuvant weekly paclitaxel and carboplatin chemotherapy, as defined by Common Toxicity Criteria (CTC)
3. Overall survival
4. Progression free survival

Patients will be followed 3 monthly for two years, patients will be evaluated clinically and toxicity assessed.

Completion date

28/11/2008

Eligibility

Key inclusion criteria

1. Histologically confirmed and reviewed at the cancer centre International Federation of Gynaecology and Obstetrics (FIGO) stage Ib2 - IVa squamous, adeno-, or adenosquamous carcinoma of the cervix suitable for radical chemoradiation

2. EUA, cystoscopy and sigmoidoscopy performed by Gynaecological Oncologist +/- Clinical Oncologist to confirm FIGO stage with biopsy of any suspicious lesions in bladder, vagina or rectum
3. Eastern Cooperative Oncology Group (ECOG) performance status 0 - 1
4. Age over 18, no upper limit, providing patient deemed fit by supervising oncologist to receive chemoradiation
5. Adequate renal function, as defined by glomerular filtration rate (GFR) estimated by EDTA or creatinine clearance (24 hour urine) greater than or equal to 60 ml/min
6. Adequate liver function, as defined by alanine aminotransferase (ALT) or aspartate aminotransferase (AST) less than 2.5 upper limit of normal (ULN), and bilirubin less than 1.25 ULN
7. Adequate bone marrow function, as defined by white cell count (WCC) greater than 3.0×10^9 /litre, neutrophils greater than 1.5×10^9 /litre, and platelets greater than 100×10^9 /litre
8. Placement of ureteric stents in all patients with hydronephrosis regardless of renal function
9. Normal electrocardiogram (ECG)
10. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. Pregnant or breast feeding patients
2. Previous diagnosis of cancer, except basal cell carcinoma (BCC) skin
3. Active cardiac disease

Date of first enrolment

14/06/2005

Date of final enrolment

28/11/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Cancer Research UK and UCL Cancer Trials Centre
London
United Kingdom
W1T 4TJ

Sponsor information

Organisation
University College London (UK)

ROR
<https://ror.org/02jx3x895>

Funder(s)

Funder type
Government

Funder Name
University College London Hospitals NHS Foundation Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/06/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes