

A prospective randomised trial of adjuvant chemotherapy in node positive early stage carcinoma of the cervix

Submission date 01/07/2001	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 01/07/2001	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 11/04/2019	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr - -

Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00003209

Protocol serial number

CE3005

Study information

Scientific Title

A prospective randomised trial of adjuvant chemotherapy in node positive early stage carcinoma of the cervix

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cervix cancer

Interventions

Following surgery patients are randomised to either:

1. Arm A: External beam pelvic radiotherapy
2. Arm B: Adjuvant chemotherapy plus external beam radiotherapy

Intervention Type

Mixed

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

28/02/1996

Eligibility**Key inclusion criteria**

1. Histologically proven invasive adeno or squamous cell carcinoma of the cervix
2. Histologically proven pelvic lymph node involvement
3. Stage Ib or IIa disease
4. Fit to receive either treatment arm
5. Adequate renal hepatic and haematological function

6. Adequate pulmonary function
7. Patients with a probability of <0.2 of not developing severe encephalopathy with ifosfamide /mensa treatment are excluded
8. No second primary tumour other than basal cell carcinoma of the skin
9. No other serious medical or psychological condition precluding treatment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1990

Date of final enrolment

28/02/1996

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information**Organisation**

Cancer Research UK (CRUK) (UK)

ROR

<https://ror.org/054225q67>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary