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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00003209

Secondary identifying numbers
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

Study design
Randomised controlled 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
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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1990

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

Age group
Not Specified

Sex
Female

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
United Kingdom
WC2A 3PX
+44 (0)207 317 5186
kate.law@cancer.org.uk

Sponsor type
Charity

Website
http://www.cancer.org.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, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location
United Kingdom

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