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A randomised trial of chemotherapy and radiotherapy versus radiotherapy alone as adjuvant treatment in women with node positive operable cancer of the cervix

Submission date 06/04/2000	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 06/04/2000	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 23/01/2019	**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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00003209

Secondary identifying numbers
CE04

Study information

Scientific Title
A randomised trial of chemotherapy and radiotherapy versus radiotherapy alone as adjuvant treatment in women with node positive operable cancer of the cervix

Study objectives
To compare post-operative cisplatin-based chemotherapy and radiotherapy with radiotherapy alone in patients with node positive stage IB or IIA cancer of the cervix.

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
1. Post-operative cisplatin-based chemotherapy and radiotherapy
2. Radiotherapy alone

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Primary endpoint is survival, defined as time from randomisation to death (from any cause).

Secondary outcome measures
Secondary endpoints are progression-free survival, site of relapse, toxicity-free survival and quality of life.

Overall study start date
01/04/1998

Completion date
25/04/2000

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Histologically confirmed cancer of the cervix with: Squamous, adenosquamous or adencarcinoma cell type/International Federation of Gynecology and Obstetrics (FIGO) stage IB or IIA/Nodal involvement (of any extent)
2. Patient fit to receive, and with no contraindication to, cisplatin-based chemotherapy
3. Patient should have undergone a radical hysterectomy, a pelvic lymphadenectomy and resection of any suspicious (enlarged) common iliac or para-aortic lymph nodes where appropriate
4. No concomitant or previous malignancy likely to interfere with protocol treatments or comparisons
5. Written informed consent

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
1000

Key exclusion criteria
1. WBC less than 3.5 x 10 to the power of 9 per litre
2. Platelets less than 100 x 10 to the power of 9 per litre
3. Bilirubin more than 1.25 times the upper limit of normal
4. Glomerular filtration rate less than 50 millilitres per minute
5. Uncontrolled or potentially active site of infection (eg fistula or abscesses)

Date of first enrolment

01/04/1998

Date of final enrolment
25/04/2000

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

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