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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

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| **Submission date**<br>06/04/2000 | **Recruitment status**<br>Stopped | [ ] Prospectively registered<br>[ ] Protocol<br>[ ] Statistical analysis plan<br>[ ] Results<br>[ ] Individual participant data<br>[ ] Record updated in last year |
| **Registration date**<br>06/04/2000 | **Overall study status**<br>Stopped | |
| **Last Edited**<br>23/01/2019 | **Condition category**<br>Cancer | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**ClinicalTrials.gov (NCT)**
NCT00003209

**Protocol serial number**
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

### Primary study design
Interventional

### Study design
Randomised controlled trial

### Study type(s)
Treatment

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

### Key secondary outcome(s)
Secondary endpoints are progression-free survival, site of relapse, toxicity-free survival and quality of life.

### 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

### Healthy volunteers allowed
No

### Age group
Not Specified

### Sex
Female

### 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
United Kingdom

England

### Study participating centre

**MRC Clinical Trials Unit**
London
United Kingdom
NW1 2DA

# Sponsor information

**Organisation**
Medical Research Council (MRC) (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, Medical Research Committee and Advisory Council, MRC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration