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# Comparison of radical radiotherapy with or without chemotherapy for poor prognosis carcinoma of cervix

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| **Submission date**<br>01/07/2001 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>01/07/2001 | **Overall study status**<br>Completed | |
| **Last Edited**<br>10/03/2015 | **Condition category**<br>Cancer | |

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

## Contact information

**Type(s)**
Scientific

**Contact name**
- - -

**Contact details**
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
G34

# Study information

### Scientific Title
Comparison of radical radiotherapy with or without chemotherapy for poor prognosis carcinoma of 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
1. Arm A: Chemotherapy with methotrexate and cisplatinum repeated every 14 days for three cycles. Radiotherapy consisting of a course of external beam therapy followed by intracavity brachytherapy to start 14 days after the third course of chemotherapy. External beam therapy, a central tumour dose of 40 Gy in twenty fractions over 4 weeks. Intracavity brachytherapy, a dose of 32.5 Gy to point A in a single insertion.

2. Arm B: Radiotherapy consisting of a course of external beam therapy followed by intracavity brachytherapy to start as soon as possible following randomisation. External beam therapy, a central tumour dose of 40 Gy in twenty fractions over 4 weeks. Intracavity brachytherapy, a dose of 32.5 Gy to point A in a single insertion.

### 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
01/01/1992

### Completion date
24/08/1997

## Eligibility

### Key inclusion criteria
1. Histologically diagnosed squamous cell carcinoma of the cervix uteri
2. International Federation of Gynecology and Obstetrics (FIGO) stage III, IVa or bulky stage II
3. No evidence of extra pelvic spread
4. Aged <70 years
5. World Health Organisation (WHO) performance 0-2
6. Suitable for radical radiotherapy
7. Suitable for chemotherapy
8. Adequate haematological and renal function
9. No history of previous malignancy, excluding successfully treated squamous and basal cell carcinoma of skin or carcinoma in situ of the cervix
10. No previous chemotherapy or radiotherapy
11. No contraindications to treatment

### Participant type(s)
Patient

### Age group
Adult

### 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
01/01/1992

### Date of final enrolment
24/08/1997

## 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