ISRCTN38929731 https://doi.org/10.1186/ISRCTN38929731

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

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 10/03/2015	**Condition category** 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
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WC2A 3PX
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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