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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

- -

Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

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, Cancer Research UK (CRUK), 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