ISRCTN26689999 https://doi.org/10.1186/ISRCTN26689999

A multicentre, randomised trial of primary chemotherapy in inoperable cervical cancer

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 01/02/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

Protocol serial number
CE3003

Study information

Scientific Title

Study objectives
Not provided at time of registration

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

Interventions
1. Arm A: Radical pelvic radiotherapy
2. Arm B: Primary chemotherapy with bleomycin, ifosfamide and cisplatinum repeated every 28 days for two courses followed by radical pelvic radiotherapy. If after two courses of chemotherapy the measurable disease has not been reduced to <2 cm diameter and if further response is expected, then a third course of chemotherapy may be given followed by radical pelvic radiotherapy.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
bleomycin, ifosfamide, cisplatin

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/12/1995

Eligibility

Key inclusion criteria
1. Histologically proven invasive squamous cell carcinoma of the cervix uteri
2. Inoperable disease, that is stage II, III or IVA. Stage IIA disease may be included if deemed inoperable by the referring gynaecologist

3. No previous treatment for invasive cervical cancer
4. World Health Organisation (WHO) performance status >2
5. Adequate renal hepatic and haematological function
6. Adequate pulmonary function
7. Patients with a probability of <0.2 of not developing severe encephalopathy with ifosfamide /mensa treatment are excluded
8. Expected survival of >3 months
9. No second primary tumour other than basal cell carcinoma of the skin
10. No other serious medical or psychological condition precluding treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1988

Date of final enrolment
31/12/1995

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Cancer Research UK (CRUK) (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2000		Yes	No