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

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

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	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/02/2012	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1988

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

Age group
Adult

Sex
Female

Target number of participants
172

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
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
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

Study outputs

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