ISRCTN27785591 https://doi.org/10.1186/ISRCTN27785591

A randomised trial of combination bleomycin, ifosfamide and cisplatinum versus single agent cisplatinum in recurrent 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 04/01/2012	**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

ClinicalTrials.gov (NCT)
NCT00003209

Protocol serial number
CE3004

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: Chemotherapy with single agent cisplatinum repeated every 21 days for a maximum of six courses.
2. Arm B: Multi-drug chemotherapy with bleomycin, ifosfamide and cisplatinum (BIP) repeated every 21 days for a maximum of six courses.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Not provided at time of registration

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

Completion date
28/02/1996

Eligibility

Key inclusion criteria
1. Histologically proven recurrent invasive squamous cell carcinoma of the cervix uteri
2. Symptomatic inoperable pelvic or metastatic disease not amenable to local radiotherapy

3. No previous chemotherapy with any of the study agents
4. World Health Organisation (WHO) performance status >2
5. Adequate renal hepatic and haematological function
6. Adequate pulmonary function
7. Expected survival of >3 months
8. No second primary tumour other than basal cell carcinoma of the skin
9. No other serious medical or psychological condition precluding treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Female

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1990

Date of final enrolment
28/02/1996

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