

A randomised trial of combination bleomycin, ifosfamide and cisplatin versus single agent cisplatin in recurrent cervical cancer

Submission date 01/07/2001	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 01/07/2001	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/01/2012	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cervix

Interventions

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