

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/07/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/01/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

NCT00003209

Secondary identifying numbers

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

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

Interventions

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

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1990

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

Age group

Not Specified

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

01/01/1990

Date of final enrolment

28/02/1996

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