

A randomised trial of chemotherapy and radiotherapy versus radiotherapy alone as adjuvant treatment in women with node positive operable cancer of the cervix

Submission date 06/04/2000	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/04/2000	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/01/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00003209

Secondary identifying numbers

CE04

Study information

Scientific Title

A randomised trial of chemotherapy and radiotherapy versus radiotherapy alone as adjuvant treatment in women with node positive operable cancer of the cervix

Study objectives

To compare post-operative cisplatin-based chemotherapy and radiotherapy with radiotherapy alone in patients with node positive stage IB or IIA cancer of the cervix.

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 cancer

Interventions

1. Post-operative cisplatin-based chemotherapy and radiotherapy
2. Radiotherapy alone

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Primary endpoint is survival, defined as time from randomisation to death (from any cause).

Secondary outcome measures

Secondary endpoints are progression-free survival, site of relapse, toxicity-free survival and quality of life.

Overall study start date

01/04/1998

Completion date

25/04/2000

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

1. Histologically confirmed cancer of the cervix with: Squamous, adenosquamous or adencarcinoma cell type/International Federation of Gynecology and Obstetrics (FIGO) stage IB or IIA/Nodal involvement (of any extent)
2. Patient fit to receive, and with no contraindication to, cisplatin-based chemotherapy
3. Patient should have undergone a radical hysterectomy, a pelvic lymphadenectomy and resection of any suspicious (enlarged) common iliac or para-aortic lymph nodes where appropriate
4. No concomitant or previous malignancy likely to interfere with protocol treatments or comparisons
5. Written informed consent

Participant type(s)

Patient

Age group

Not Specified

Sex

Female

Target number of participants

1000

Key exclusion criteria

1. WBC less than 3.5×10^9 per litre
2. Platelets less than 100×10^9 per litre
3. Bilirubin more than 1.25 times the upper limit of normal
4. Glomerular filtration rate less than 50 millilitres per minute
5. Uncontrolled or potentially active site of infection (eg fistula or abscesses)

Date of first enrolment

01/04/1998

Date of final enrolment

25/04/2000

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

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clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

<http://www.mrc.ac.uk>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

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