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A study of potentially curative local therapy alone, or preceded by chemotherapy, in the treatment of Stage Ib-IVa cervical carcinoma

Submission date 28/02/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/02/2001	**Overall study status** Completed	
Last Edited 31/07/2009	**Condition category** Cancer	

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

Secondary identifying numbers
CeCa

Study information

Scientific Title

Study objectives
This study aims to address the question of whether neo-adjuvant chemotherapy provides a survival advantage over local treatment alone in patients with cervical carcinoma.

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)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cervical cancer

Interventions
Chemotherapy patients randomised to chemotherapy, will receive this treatment prior to local therapy. Chemotherapy will consist of: cisplatin (50 mg/m^2), methotrexate (100 mg/m^2) and folinic acid (15 mg orally every six hours, to commence 30 hours after the start of intravenous cisplatin and methotrexate, for eight doses). Cisplatin and methotrexate will be given intravenously for three cycles, once every two to three weeks depending upon tolerance. Adequate hydration should be given before and after administration of cisplatin. No immediate chemotherapy (local therapy). Because of the diversity of approach with regard to surgery and especially radiotherapy, no specific schedule will be laid down.

However all patients entering the study should receive radical local treatment which is regarded as potentially curative within that situation. Ideally, each institution should use a standard treatment policy throughout the study. Local therapy should be started as soon as possible after diagnosis or within three weeks of completing chemotherapy in those patients randomised to chemotherapy.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Cisplatin, methotrexate and folinic acid

Primary outcome measure
Survival and time to recurrence

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1991

Completion date
03/11/1995

Eligibility

Key inclusion criteria
1. Histologically proven invasive cancer of the cervix Stage Ib through to IVa
2. Patients must be fit enough to receive adjuvant chemotherapy, and the chosen definitive treatment
3. World Health Organisation (WHO) performance status zero to one or creatinine clearance of at least 60 ml/min
4. The informed consent of the patient

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
313 participants intended, only 48 randomised.

Key exclusion criteria
1. Previous chemotherapy
2. Renal, hepatic or bone marrow dysfunction which in the opinion of the investigator is sufficient to prejudice therapy (including local treatment and chemotherapy
3. Previous malignancy other than basal cell carcinoma
4. Medical or psychological conditions precluding treatment

Date of first enrolment
01/01/1991

Date of final enrolment
03/11/1995

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
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Sponsor information

Organisation
Medical Research Council (MRC) (UK)

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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Trial not published on its own. The results were published in the meta-analysis entitled Neoadjuvant chemotherapy for locally advanced cervical cancer: a systematic review and meta-analysis of individual patient data from randomised trials. Neoadjuvant Chemotherapy for Cervical Cancer Meta-analysis Collaboration (European Journal of Cancer 39 [2003] 2470-2486) - see	01/11/2003		Yes	No