

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	<input type="checkbox"/> Prospectively registered
Registration date 28/02/2001	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 31/07/2009	Condition category Cancer	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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/m²), methotrexate (100 mg/m²) 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(s)

Survival and time to recurrence

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation

Medical Research Council (MRC) (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output
type Details

Date Date Peer Patient-
created added reviewed? 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
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