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A randomised trial of lymphadenectomy and of adjuvant external beam radiotherapy in endometrial cancer

Submission date	Recruitment status	[_] Prospectively registered
06/04/2000	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/04/2000	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/10/2018	Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ctu.mrc.ac.uk/studies/ASTEC.asp

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00003749

Secondary identifying numbers
UT01

Study information

Scientific Title
A randomised trial of lymphadenectomy and of adjuvant external beam radiotherapy in endometrial cancer

Acronym
ASTEC

Study objectives
1. To determine the benefit or otherwise of lymphadenectomy in patients with endometrial cancer (thought pre-operatively to be confined to the corpus).
2. To determine the benefit or otherwise of post-operative adjuvant radiotherapy in patients with endometrial cancer, high risk pathology and no macroscopic disease following surgery

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
Cancer

Interventions
There are four groups:
1. The first group receives standard surgery alone.
2. The second group receives standard surgery plus lymphadenectomy

3. The third group receives standard surgery plus (external beam) radiotherapy
4. The fourth group receives standard surgery plus lymphadenectomy plus (external beam) radiotherapy.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Primary endpoint is survival.

Secondary outcome measures
Secondary endpoints are recurrence-free survival and quality of life.

Overall study start date
01/04/1998

Completion date
01/01/2005

Eligibility

Key inclusion criteria
Surgical randomisation inclusion:
1. Histologically proven diagnosis of endometrial carcinoma
2. Disease thought pre-operatively to be confined to the corpus (CT or MRI scanning suggesting node enlargement is not an exclusion to randomisation and should not influence the decision to randomise)
3. Patient fit to undergo lymphadenectomy
4. Centre able to offer appropriate surgery
5. Patient fit to receive external beam radiotherapy
6. Written informed consent (for randomisation into both surgical and radiotherapy components).

Radiotherapy randomisation inclusion:
1. Histologically proven diagnosis of endometrial carcinoma
2. Disease pre-operatively confined to the corpus
3. Macroscopically free of disease (positive para-aortic nodes should be viewed as indicative of further [unseen] macroscopic disease)
4. Fit to receive external beam radiotherapy
5. High risk pathology, assessed independently of nodal status, defined as one or more of the following: Grade 3 (poorly differentiated) or Invasion to the outer half of the myometrium or Serous papillary or clear cell type or Stage IIA
6. Written informed consent.

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
2,300

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/04/1998

Date of final enrolment
01/01/2005

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
20 Park Crescent
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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 (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?
Plain English results				No	Yes
Results article	pooled trial results, systematic review and meta-analysis of STEC and NCIC CTG EN.5 trials:	10/01/2009		Yes	No

Results article	results	10/01/2009	Yes	No