

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

Submission date 06/04/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/04/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/10/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

Contact name

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Contact details

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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

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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 (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