

A randomised, double blind trial to assess the morphological and biological effects with Arimidex, compared to placebo when used as neoadjuvant treatment for patients with endometrial cancer

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/02/2018	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

Protocol serial number
N0436125539

Study information

Scientific Title

A randomised, double blind trial to assess the morphological and biological effects with Arimidex, compared to placebo when used as neoadjuvant treatment for patients with endometrial cancer

Study objectives

To investigate the therapeutic effects of Arimidex in endometrial cancer. Primary objective - to assess the volume of endometrial cancer in both the Arimidex and placebo arm, and to compare the biology of the endometrial cancer in both arms.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised placebo-controlled parallel-group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Endometrial cancer

Interventions

Randomised controlled trial. Random allocation to [A] Arimidex [B] placebo

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Anastrozole (Arimidex®)

Primary outcome(s)

1. Alteration in endometrial cancer volume as determined by MRI
2. Alteration in immunohistochemical markers of proliferation and apoptosis

Key secondary outcome(s)

1. Incidence of side effects
2. Number of lymph node positive cases at surgical staging

Completion date

31/07/2006

Eligibility

Key inclusion criteria

Patients for this study will be recruited from a number of selected gynaecology/oncology units in the Yorkshire Strategic Health Authority. No formal power calculation is possible as there is no information or literature in this research. An arbitrary figure of 60 patients has been chosen based on 30% accrual from the patient population. Currently 203 patients per year are registered in the Yorkshire region. Of these, 84% undergo surgery ($n = 170$) and therefore eligible to participate. In order to produce more information on the Arimidex arm the patients will be randomised on a 2:1 basis to either Arimidex or placebo.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/04/2003

Date of final enrolment

31/07/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

St James's University Hospital

Leeds

United Kingdom

LS9 7TF

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Leeds Teaching Hospitals NHS Trust (UK)

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 created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes