

# 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

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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### **Secondary study design**

Randomised parallel trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

### **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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/04/2003

**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

**Age group**

Adult

**Sex**

Female

**Target number of participants**

170

**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**

England

United Kingdom

**Study participating centre**

**St James's University Hospital**

Leeds

United Kingdom

LS9 7TF

## **Sponsor information**

**Organisation**

Department of Health

**Sponsor details**

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/Home/fs/en>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

## 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