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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	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 19/02/2018	**Condition category** Cancer	[ ] Individual participant data [ ] 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 immumohistochemical 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 form 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%b undergo surgery (n = 170) and therefore eligible to participate. In order to produce more information on the Arimimdex 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

Leeds Teaching Hospitals NHS Trust (UK)

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