ISRCTN80827145 https://doi.org/10.1186/ISRCTN80827145

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

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

Primary study design
Interventional

Study design
Randomised placebo-controlled parallel-group trial

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 immumohistochemical 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 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

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