ISRCTN46431737 https://doi.org/10.1186/ISRCTN46431737

The application of the levonorgestrel containing intrauterine contraceptive device in the prevention of endometrial changes induced by tamoxifen in women undergoing adjuvant therapy for breast cancer

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 13/02/2018	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr J Konje

Contact details
University Hospitals of Leicester
c/o Research and Development Office
Leicester General Hospital NHS Trust
Leicester
United Kingdom
LE1 4PW
+44 (0)116 258 4109
nicola.turner@uhl-tr.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0123109192

Study information

Scientific Title
The application of the levonorgestrel containing intrauterine contraceptive device in the prevention of endometrial changes induced by tamoxifen in women undergoing adjuvant therapy for breast cancer

Study objectives
To find out whether giving this treatment at the time of initiation of tamoxifen treatment will prevent the changes induced by this drug from developing in the first instance.

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

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Randomised controlled trial: prior to tamoxifen treatment, patient will receive either:
1. Levonorgestrel-containing intrauterine contraceptive device
2. Placebo

Intervention Type

Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Levonorgestrel, tamoxifen

Primary outcome measure
Data not yet available.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2002

Completion date
31/12/2007

Eligibility

Key inclusion criteria
Data not yet available.

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2002

Date of final enrolment
31/12/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
University Hospitals of Leicester
Leicester
United Kingdom
LE1 4PW

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
University Hospitals of Leicester 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2009		Yes	No