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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

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Data not yet available.

Key secondary outcome(s))
Not provided at time of registration

Completion date

31/12/2007

Eligibility

Key inclusion criteria
Data not yet available.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Female

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
University Hospitals of Leicester 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?
Results article	results	01/09/2009		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes