

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
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 13/02/2018	Condition category Cancer	☐ Individual participant data

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

Primary study design

Interventional

Study design

Randomised controlled trial

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