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A randomised trial of zoladex plus raloxifene plus screening versus screening alone for the prevention of breast cancer in premenopausal women at high genetic risk

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 28/01/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.cancer.gov/clinicaltrials/NCRI-IBIS-RAZOR

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00031850

Secondary identifying numbers
IBIS-RAZOR

Study information

Scientific Title
A randomised trial of zoladex plus raloxifene plus screening versus screening alone for the prevention of breast cancer in premenopausal women at high genetic risk

Study objectives
Not provided at time of registration

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Interventions
4 weeks of raloxifene tablets to be taken once daily given at visit for Zoladex injection. Zoladex 3.6 g/month plus raloxifene 60 mg/day versus No medical treatment

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Zoladex, Raloxifene

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/2000

Completion date
31/05/2005

Eligibility

Key inclusion criteria
1. Aged 30-45 years at time of randomisation
2. Intact ovarian function; follicle-stimulating hormone (FSH) in premenopausal range if not menstruating
3. High genetic risk of breast cancer established by:
a) BRCA1 germ-line mutation
b) BRCA2 germ-line mutation
c) first-degree relative of known BRCA1/2 mutation carrier
d) family with four or more affected relatives with female or male breast cancer or ovarian cancer below age 60
e) two first-degree relatives diagnosed with breast cancer below age 40
f) p53 germ-line mutation (classical Li-Fraumeni syndrome [LFS] only) or first-degree relative of a carrier in a family with classical LFS
g) risk equivalent to the above confirmed by a clinical geneticist
4. Baseline mammography which shows no evidence of breast cancer. Malignancy of suspicious lesions must be excluded
5. Acceptable liver and renal function
6. Accessible for follow-up
7. Life expectancy >10 years
8. Informed consent
9. If heterosexually active use of non-hormonal contraception

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
150

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/05/2000

Date of final enrolment
31/05/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Cancer and Enabling Sciences
Manchester
United Kingdom
M20 4BX

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
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WC2A 3PX
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Sponsor type
Charity

Website
http://www.cancer.org.uk

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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	01/01/2018	28/01/2019	Yes	No