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United Kingdom Familial Ovarian Cancer Screening Study

Submission date	Recruitment status	[_] Prospectively registered
29/04/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/03/2022	Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-ovarian-cancer-screening-for-women-at-high-risk-the-united-kingdom-familial-ovarian-cancer-screening-study

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00033488

Protocol serial number
1069; Current Version 10.0

Study information

Scientific Title
A non-randomised interventional screening trial for women at high risk of ovarian/fallopian tube cancer

Acronym
UK FOCSS

Study objectives
5,000 women at high risk of ovarian/fallopian tube cancer due to a strong family history or known mutation in predisposing genes are being screened annually with transvaginal ultrasound and every four months with the serum tumour marker CA125. CA125 levels are processed using a Risk of Ovarian Cancer Algorithm (ROCA), which stratifies women according to their age, menopausal status and pattern of CA125 over time. Women with intermediate ROCA results have a repeat ultrasound. Women with suspicious scans or highly elevated ROCA results are referred to a gynaecologist for consideration of surgical investigation. Screening is coordinated from University College London via an online database accessible by collaborating national centres. All CA125 tests are processed centrally at UCL. The aims of the research are to develop an optimised screening procedure for ovarian cancer in high-risk women, to determine the physical morbidity, resource implications and feasibility of screening this high-risk population and to establish a serum bank for future assessment of novel tumour markers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 4 REC, 11/12/2001, ref: 97/5/007

Study design
Non-randomised interventional screening trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network, Primary Care Research Network for England, Congenital Disorders; Subtopic: Gynaecological Cancer, Not Assigned, Congenital Disorders (all Subtopics); Disease: Ovary, Clinical Genetics, All Diseases

Interventions
Intervention comprised of two screening tests:
1. 4-monthly CA125 blood tests
2. An annual transvaginal ultrasound scan
Study entry: registration only

Updated 23/10/2018:
Phase 1: Annual screening
Phase 2: Four-monthly screening

Intervention Type
Other

Phase
Phase I

Primary outcome(s)
Diagnosis/stage/grade of primary invasive epithelial ovarian/fallopian tube cancer, measured during and one year after the end of active screening (June 2012)

Key secondary outcome(s))
No secondary outcome measures

Completion date
31/12/2020

Eligibility

Key inclusion criteria
Inclusion in the study will be on the basis of a family history of cancer confirmed by histopathology report or death certification or a documented mutation of an OC causing gene. The UK FOCSS inclusion criteria have been devised to include all women who have a greater than or equal to 10% life time risk of ovarian cancer. This corresponds to a BRCA carrier probability of greater than or equal to 25% in the volunteer or greater than or equal to 50% in a FDR (first degree relative) of the volunteer including:
1. Families with ovarian or ovarian and breast cancer
2. Families with a known gene mutation
3. Families with colorectal cancer (HNPCC or Lynch syndrome)
4. Families with only breast cancer
5. Families with Ashkenazi Jewish ethnicity (additional criteria). Full details available from co-ordinating centre.
6. Female, aged between 35 and 75 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Past history of bilateral salpingo-oophorectomy (N.B. Women who have undergone bilateral oophorectomy but who still have one or more Fallopian Tube in situ are eligible as they may be at increased risk of Fallopian Tube Cancer)
2. Less than 35 years of age
3. Women participating in other OC screening trials

Date of first enrolment
05/06/2002

Date of final enrolment
30/04/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
UCL Faculty of Biomedical Sciences
London
United Kingdom
W1T 7JA

Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) (ref: C1005/A6383)

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

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
The Eve Appeal (UK)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2012		Yes	No
Results article	results	01/12/2012		Yes	No
Results article	results	01/01/2013		Yes	No

Results article	results	01/03/2013		Yes	No
Results article	results	01/11/2013		Yes	No
Results article	results	01/11/2013		Yes	No
Results article	results	27/08/2015		Yes	No
Results article	results	09/09/2015		Yes	No
Results article	results	10/09/2015		Yes	No
Results article	results	17/01/2017		Yes	No
Results article	results	01/05/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			31/03/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes