

# United Kingdom Familial Ovarian Cancer Screening Study

<b>Submission date</b> 29/04/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/03/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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>

## Study website

<http://ukfocss.org.uk/>

## Contact information

### Type(s)

Scientific

### Contact name

Prof Usha Menon

### ORCID ID

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

NCT00033488

**Secondary identifying numbers**

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

**Secondary study design**

Non randomised study

**Study setting(s)**

GP practice

**Study type(s)**

Screening

## **Participant information sheet**

Can be found at [http://www.instituteforwomenshealth.ucl.ac.uk/academic\\_research/gynaecologicalcancer/gcrc/ukfocss/pis.pdf](http://www.instituteforwomenshealth.ucl.ac.uk/academic_research/gynaecologicalcancer/gcrc/ukfocss/pis.pdf)

## **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 measure**

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

## **Secondary outcome measures**

No secondary outcome measures

## **Overall study start date**

05/06/2002

## **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

**Age group**

Adult

**Sex**

Female

**Target number of participants**

Planned Sample Size: 5000; UK Sample Size: 5000

**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**

England

United Kingdom

**Study participating centre**

UCL Faculty of Biomedical Sciences

London

United Kingdom

W1T 7JA

**Sponsor information**

**Organisation**

University College London Hospitals NHS Foundation Trust (UK)

**Sponsor details**

Joint UCLH/UCL Biomedical Research Unit  
1st Floor Maple House  
149 Tottenham Court Road  
London  
England  
United Kingdom  
W1P 9LL

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.ucl.ac.uk/joint-rd-unit/>

**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, 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

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

Not provided at time of registration

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/01/2012		Yes	No
<a href="#">Results article</a>	results	01/12/2012		Yes	No
<a href="#">Results article</a>	results	01/01/2013		Yes	No
<a href="#">Results article</a>	results	01/03/2013		Yes	No
<a href="#">Results article</a>	results	01/11/2013		Yes	No
<a href="#">Results article</a>	results	01/11/2013		Yes	No
<a href="#">Results article</a>	results	27/08/2015		Yes	No
<a href="#">Results article</a>	results	09/09/2015		Yes	No
<a href="#">Results article</a>	results	10/09/2015		Yes	No
	results				

<a href="#">Results article</a>		17/01/2017		Yes	No
<a href="#">Results article</a>	results	01/05/2017		Yes	No
<a href="#">Plain English results</a>			31/03/2022	No	Yes