# United Kingdom Familial Ovarian Cancer Screening Study

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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

#### Contact name

Prof Usha Menon

#### **ORCID ID**

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## Contact details

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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 coordinating 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