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Predicting risk of ovarian malignancy improved screening and early detection feasibility study

Submission date
05/06/2017

Recruitment status
No longer recruiting

Registration date
20/06/2017

Overall study status
Completed

Last Edited
30/07/2025

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Ovarian cancer, or cancer of the ovaries, is one of the most common types of cancer in women. Over 7000 UK women get ovarian cancer every year in the UK and over 4000 die from it. 7 in 10 women still present with advanced disease, which has poor survival. The aims of this study are to assess the feasibility of offering all women the opportunity to find out about their risk of developing ovarian cancer; to assess the interest, acceptability and satisfaction with this process; to assess the impact of providing women with their risk of ovarian cancer; and to assess the use of early detection (screening) and preventive options by women identified to be at increased risk.

Who can participate?
Women aged over 18 who have not had ovarian cancer, tubal cancer, primary peritoneal cancer or a genetic test looking for gene alterations that increase the risk of ovarian cancer.

What does the study involve?
Interested women access a specially designed web-based ‘decision aid’ and have access to a telephone helpline to help them decide if they wish to participate in this study. Women who consent are asked to provide health-related information and a blood sample for genetic testing for known ovarian cancer genes. These include genes which significantly affect risk, as well as a number of other minor faults which have a small effect on ovarian cancer risk. The genetic test results and health information provided are used in a specially developed mathematical model to predict a woman’s ovarian cancer risk. Women found to be intermediate or high risk are offered options of screening (early detection) and prevention through a specialist clinic at Barts Health NHS Trust. Early detection involves a combination of blood tests and an ultrasound scan. Prevention can involve an operation to remove the tubes and ovaries (once family is complete). Participants fill in follow up questionnaires for up to 6 months regarding their satisfaction, acceptability, experience and impact on health and well-being from participating in this study.

What are the possible benefits and risks of participating?
It is hoped that this approach of identifying more women at increased risk and offering options of early detection and prevention can improve outcomes or prevent women from getting ovarian cancer itself. However, it is important to understand the pros and cons as well as the

impact of such an approach in a study in a wider population before such a strategy can be introduced. This study will provide information on feasibility and help with the design of a larger study. Possible benefits of participating include the opportunity for women to find out if they are at a 'high', 'intermediate' or 'low risk' of developing ovarian cancer and opt for screening and prevention if found to be at increased risk. Participants also contribute to research efforts to reduce ovarian cancer in women. Drawbacks of participating include the possibility of mixed or negative emotions in some women who receive a positive result, such as feeling frightened, upset, anxious, guilty or depressed, and a potential impact on insurance or marriage prospects. Participants opting for ovarian cancer screening may receive an abnormal marker or ultrasound result despite there being no cancer, causing increased anxiety or upset. Cancer is identified in 1 in 3 to 1 in 10 women who have an operation following an abnormal screening test, so some women may have unnecessary surgery. Removal of the tubes and ovaries prevents ovarian cancer but leads to early menopause in women who are pre-menopausal. This can cause hot flushes, sweats, reduced libido, thinning of the bones and a higher risk of heart disease. These side effects can be minimised by hormone replacement therapy. The operation has a low (3-4%) complication rate.

Where is the study run from?
1. Barts Cancer Institute & Barts Health NHS Trust (UK)
2. Redbridge Primary Care Trust (UK)

When is the study starting and how long is it expected to run for?
May 2017 to May 2024

Who is funding the study?
1. Cancer Research UK
2. The Eve Appeal

Who is the main contact?
1. Dr Ranjit Manchanda (scientific)
r.manchanda@qmul.ac.uk
2. Dr Faiza Gaba (public)
f.gaba@qmul.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Ranjit Manchanda

ORCID ID
https://orcid.org/0000-0003-3381-5057

Contact details
Barts Cancer Institute
Queen Mary University of London
Room 4, Basement, Old Anatomy Building
Charterhouse Square
London

United Kingdom
EC1M 6BQ
+44 (0)797 372 3455
r.manchanda@qmul.ac.uk

Type(s)
Public

Contact name
Dr Faiza Gaba

Contact details
Centre for Experimental Cancer Medicine
Barts Cancer Institute
Queen Mary's University of London
Old Anatomy Building
Charterhouse Square
London
United Kingdom
EC1M 6BQ
+44 (0)797 372 3455
f.gaba@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number
208219

ClinicalTrials.gov number

Secondary identifying numbers
IRAS project ID: 208219

Study information

Scientific Title
Predicting risk of ovarian malignancy improved screening and early detection feasibility study: a multi-centre prospective pilot cohort study

Acronym
PROMISE-FS

Study objectives
It is feasible to undertake a study to offer all women the opportunity to find out about their risk of developing ovarian cancer as well as offer risk management options of screening and prevention.

Ethics approval required

Old ethics approval format

Ethics approval(s)
London - Central Research Ethics Committee, 30/01/2017, ref: 16/LO/2075

Study design
Multi-centre prospective pilot cohort study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Prevention of ovarian cancer

Interventions
Potential participants who have met the study's inclusion/exclusion criteria and who have expressed interest in the study after receiving a flyer from their GP practice will contact the research team using the contact details (telephone number/email/address) provided on the flyer.

Decision Aid: Interested participants will then be provided access to an online ‘Decision Aid’ which is designed to help the individual decide if she wishes to participate in the study or not. A helpline access is provided for queries. Should the individual wish to participate in the study, telephone consent (consent form-1) will be obtained using a 'telephone helpline'.

Genetic testing: After consent, a blood sample for a panel genetic test will be taken. DNA will be extracted from the blood samples and tested for known ovarian cancer gene mutations: BRCA1, BRCA2, RAD51C, RAD51D and BRIP1 as well as the known ovarian cancer SNPs.

Baseline Questionnaire: Participants will also be given a baseline questionnaire to fill in and return by free post. This will gather information about their medical, reproductive and family history.

Epidemiological information gathered from the baseline questionnaire along with results of the panel genetic test will be used by a computerised risk prediction algorithm developed in the PROMISE programme to calculate an individual’s absolute risk of developing ovarian cancer. Women will be categorised based on their absolute risk of ovarian cancer as high, intermediate or low risk of ovarian cancer.

Women found to be at intermediate risk (>5% - <10% life time risk of ovarian cancer) or high risk (≥10% life time risk of ovarian cancer) will be informed of their results at a face to face consultation at a specialist Familial Cancer Clinic. Various options will be discussed:
1. Lifestyle advice
2. Ovarian screening: based on transvaginal ultrasound scan and 4 monthly longitudinal biomarker analysis
3. Prevention: Risk reducing salpingo-oophorectomy (RRSO)
4. BRCA1/BRCA2 carriers identified will also be offered breast screening (mammography/MRI)

If required, specialist input from a psychologist, menopause specialist or breast clinician will be available for the individual.

All moderate/high penetrance mutations detected in the research study will undergo confirmatory testing in a NHS genetics laboratory.

Low-risk women (0-5% life time risk of ovarian cancer) will be posted their results. A small proportion will be randomly selected to be told their results in clinic. They will not require any follow up.

Follow up Questionnaires: Follow-up questionnaires will be posted to out to volunteers at 7 days, 3 months and 6 months post results to evaluate attitude, risk perception, cancer worry, satisfaction, impact on psychological health and quality of life as well as their views on the decision aid and telephone helpline. The follow-up completion rate will be assessed.

Women who chose not to participate in the study after viewing the Decision Aid will be given the option to sign consent form 2 to enable the research team to collect additional information on the volunteer's views of the decision aid, telephone helpline and reasons for not wishing to participate in the study. This is optional.

Intervention Type
Mixed

Primary outcome measure
Acceptability and uptake of the study:
1. Acceptability measured by responses to the decision aid questions and overall score (prior to consent)
2. Uptake measured as number of individuals who express interest in participating in the study (by post/email/telephone) who sign consent form 1

Secondary outcome measures
1. Use of helpline, measured by the proportion of individuals using the helpline during the study and by the helpline evaluation questionnaire
2. Risk perception and cancer worry, measured using cancer risk perception and ovarian cancer worry scale questionnaires at baseline, 7 days post results, 3 and 6 months post results for participating individuals (consent form 1), and at study exit for those declining participation (sign consent form 2)
3. Psychological health and quality of life, measured using HADS and EQ5D-5L at baseline, 7 days, 3 and 6 months post results for participating individuals (consent form 1), IES (Impact of Events Scale) used at 7 days, 3 months and 6 months post results for participating individuals, and measured using HADS and EQ5D-5L questionnaires at study exit for those declining participation (consent form 2)

4. Usefulness of decision aid, measured using decision aid evaluation questionnaire post recruitment for participating individuals (consent 1) and at study exit for those declining participation (consent 2)
5. Stratification of ovarian cancer risk category: individuals stratified as high/intermediate/low risk by risk prediction algorithm (post panel genetic test results)
6. Uptake of risk management options, measured as the number of individuals who are intermediate/high risk who accept screening/risk reducing surgery post risk prediction algorithm stratification
7. Satisfaction/regret, measured using decision regret scale questionnaire 3 months post results for participating individuals (consent 1), and using decision regret scale questionnaire at study exit for those declining participation (consent form 2)
8. Follow-up completion rate, measured at study end as the number of individuals who after consenting to participate in the study (consent 1), have the panel genetic test and receive the ovarian cancer test result. The proportion of completed and returned questionnaires is also measured

Overall study start date
09/06/2017

Completion date
01/05/2024

Eligibility

Key inclusion criteria
Women aged ≥18 years

Participant type(s)
All

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
140

Total final enrolment
123

Key exclusion criteria
1. Past history of tubal cancer/ovarian cancer/primary peritoneal cancer
2. Personal history of genetic testing for ovarian cancer predisposing genes

Date of first enrolment

09/06/2017

Date of final enrolment
20/11/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Barts Cancer Institute & Barts Health NHS Trust
Charterhouse Square
London
United Kingdom
EC1M 6BQ

Study participating centre
Redbridge Primary Care Trust (PCT)
Beckett House
2-14 Ilford Hill
Ilford
London
United Kingdom
IG1 2QX

Sponsor information

Organisation
Queen Mary University of London

Sponsor details
Joint Research Management Office
QM Innovation Building
5 Walden Street
London
England
United Kingdom
E1 2EF
+44 (0)20 7882 7260
sponsorsrep@bartshealth.nhs.uk

Sponsor type
University/education

Website
http://www.qmul.ac.uk/jrmo/

ROR
https://ror.org/026zzn846

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

Funder Name
The Eve Appeal

Results and Publications

Publication and dissemination plan
Results of the research will be presented at scientific conferences and published in scientific journals. They will also be made available through cancer charities, patient support groups and the Queen Mary University of London website.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	qualitative results presented at the European Society of Gynaecological Oncology (ESGO) conference	01/11/2019	20/01/2021	No	No
HRA research summary			28/06/2023	No	No
Other publications	Qualitative study of unselected population genetic testing for personalised ovarian cancer risk prediction	19/04/2022	30/07/2025	Yes	No
Results article		15/05/2020	30/07/2025	Yes	No