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Views of women at increased risk of ovarian cancer towards removal of fallopian tubes for ovarian cancer prevention

Submission date
08/02/2018

Recruitment status
No longer recruiting

Registration date
09/02/2018

Overall study status
Completed

Last Edited
20/01/2021

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 is the main cause of death from gynaecological malignancies in the UK. Despite massive funding in developing drugs and new treatment strategies, survival rates remain much poorer when compared to other cancers with 3 in 10 women alive at 10 years. In addition, 1 in 10 of all ovarian cancer is familial and most commonly caused by a fault/alteration in the BRCA1 or BRCA2 gene. BRCA1/BRCA2 carriers have a 17-44% risk over their life of developing ovarian cancer and 65-72% risk of developing breast cancer. This is much higher than for women who do not carry the gene who have a 1 in 50 (2%) and a 1 in 8 (12%) lifetime risk of developing ovarian and breast cancer respectively. Focusing on developing strategies to prevent ovarian cancer in women at increased risk may have a significant impact on disease burden. There is currently no screening programme for ovarian cancer available on the NHS unlike other female cancers such as cervical and breast cancer. The current practice is to offer women who are at increased risk, once they have completed their family, surgery to remove their fallopian tubes and ovaries. This procedure is called risk reducing salpingo-oophorectomy (RRSO). This significantly reduces the risk of ovarian cancer by 90% but leads to early menopause. This has serious implications on a woman's general health. Not only does early menopause result in menopausal type symptoms such as hot flushes, changes in mood and pain during intercourse, it also increases the risk of osteoporosis (brittle bones), heart disease, stroke and dementia. Current research suggests that many cancers of the ovary actually start in the fallopian tube. This has led to the proposal of an alternative strategy which involves offering women surgery in two stages. The first operation involves removing the fallopian tubes. The second operation involves removing the ovaries after the patient has gone through the menopause (average age 51 in the UK). The advantage of this new surgical prevention strategy is that it offers some protection against ovarian cancer in young women whilst avoiding the negative health consequences of early menopause which can have a significant impact on quality of life. At present the precise level of benefit obtained from removing the tubes alone is not known. There are no research studies to show whether this two-stage procedure is acceptable and effective for preventing ovarian cancer. Further research is needed to establish this. The aim of this study is to collect the views of women at increased risk on this ‘two-stage’ strategy to prevent ovarian cancer.

Who can participate?
Women aged over 18, living in the UK who are at increased risk of developing tubal/ovarian cancer because they carry an alteration/fault in the BRCA1/BRCA2/RAD51C/RAD51D/BRIP1 gene or have a strong family history of breast and ovarian cancer or ovarian cancer alone

What does the study involve?
Participants complete an online or paper questionnaire to gather information about their attitudes towards the two-staged surgical approach to reduce the risk of ovarian cancer. The questionnaire is conducted just once per participant. There are no follow up questionnaires.

What are the possible benefits and risks of participating?
Participants will help researchers understand how women feel about this new two-staged surgical approach of preventing ovarian cancer. It will help develop future research studies for ovarian cancer prevention and benefit the health of women at increased risk of ovarian cancer in the future. The drawback to participating is the inconvenience of completing a questionnaire.

Where is the study run from?
Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?
October 2017 to March 2020

Who is the main contact?
1. Dr Ranjit Manchanda (scientific)
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Contact information

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Scientific

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0

Study information

Scientific Title
Survey to determine attitudes of women at high risk of ovarian cancer towards Risk Reducing Early Salpingectomy and Delayed Oophorectomy (RRESDO) for ovarian cancer prevention

Study objectives
Risk reducing early salpingectomy with delayed oophorectomy is an acceptable surgical prevention strategy for women who are at increased risk of ovarian cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Edgbaston Research Ethics Committee, 21/08/2017, REC ref: 17/WM/0324

Study design
Prospective cohort survey study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

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
Participants who have met the study's inclusion/exclusion criteria and who have provided informed consent will be given a questionnaire to complete. This will gather information about their attitudes towards a novel two staged surgical approach (risk reducing early salpingectomy with delayed oophorectomy) to reduce the risk of ovarian cancer. The questionnaire may be completed online or using a paper version. The questionnaire is conducted just once per participant. There are no follow up questionnaires.

Intervention Type
Other

Primary outcome measure
Awareness and interest in an early salpingectomy and delayed oophorectomy strategy for ovarian cancer prevention, measured using a questionnaire at a single timepoint

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
30/10/2017

Completion date
01/03/2020

Eligibility

Key inclusion criteria
Current inclusion criteria as of 09/05/2018:
1. Women ≥18 years
2. At increased risk of developing ovarian cancer due to BRCA1/BRCA2/RAD51C/RAD51D/BRIP1 mutation or on the basis of a strong family history of ovarian cancer alone or breast and ovarian cancer
3. Resident in the UK
4. Able to provide written informed consent

Previous inclusion criteria:
1. Women ≥18 years
2. At increased risk of developing ovarian cancer due to BRCA1/BRCA2 mutation or on the basis of family history
3. Resident in the UK
4. Able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Up to 1000

Total final enrolment
683

Key exclusion criteria
1. Prior or current diagnosis of tubal/ ovarian/primary peritoneal cancer
2. Inability to read or write

Date of first enrolment
04/01/2018

Date of final enrolment
04/06/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Barts Health NHS Trust
St Bartholomew's Hospital
West Smithfield

London
United Kingdom
EC1A 7BE

Study participating centre
University College Hospital
235 Euston Road
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Sponsor information

Organisation
Queen Mary University of London

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Joint Research Management Office
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Sponsor type
University/education

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

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Additional documents e.g. protocol are not published. They will not be made available unless specific requests for additional information are made to the chief investigator Ranjit Manchanda in writing. 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
01/12/2020

Individual participant data (IPD) sharing plan
The 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?
Results article	results	01/03/2021	20/01/2021	Yes	No
HRA research summary			28/06/2023	No	No