ISRCTN16988857 https://doi.org/10.1186/ISRCTN16988857

Systematic genetic testing for personalised ovarian cancer therapy (SIGNPOsT)

Submission date 07/06/2017	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 29/06/2017	**Overall study status** Ongoing	
Last Edited 27/09/2023	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-genetic-testing-for-ovarian-cancer-signpost

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
ReDA11776

Study information

Scientific Title
SystematIc GeNetic testing for Personalised Ovarian cancer Therapy: A prospective cohort study investigating the impact of systematic germline panel and concomitant somatic testing in epithelial ovarian cancer on psychological health and quality of life

Acronym
SIGNPOsT

Study objectives
Null hypothesis:
There is no difference in psychological health between mutation carriers detected on panel-based genetic testing and concomitant somatic testing (of high grade non-mucinous epithelial ovarian cancer) compared to non-carriers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Committee - London Riverside, 29/03/2017, ref: 17/LO/0405

Study design
Prospective cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Epithelial ovarian cancer

Interventions
Participants attend a baseline visit where they undergo systematic genetic germline panel testing for BRCA1, BRCA2, RADL51C, RAD51D, BRIP1 gene mutations and concomitant somatic genetic testing for BRCA1 and BRCA2. They also have demographic data, family history and clinical outcomes collected. Participants are asked to fill out surveys about their anxiety, quality of life, and counselling satisfaction scale. Participants who decline the genetic test complete a survey called "reasons for declining genetic test". This visit takes around 55-60 minutes.

After the results of the genetic testing is complete, participants then repeat the anxiety and quality of life surveys as well as have a psychological health test using the Multi-dimensional impact of Cancer Risks Assessment (MICRA) scale. This visit takes around 30 minutes.

Six months after the test, participants again repeat the anxiety and quality of life surveys as well as have a psychological health test using the Multi-dimensional impact of Cancer Risks Assessment (MICRA) scale. This visits takes around 30 minutes.

Participants then are asked to attend annual visits where they are surveyed for their patient satisfaction and if they regret their decisions. Participants again repeat the anxiety and quality of life tests. Only at the first annual visit since the genetic testings, participants again complete the MICRA test to have their psychological health assessed.

The total follow up period is five years.

Intervention Type
Behavioural

Primary outcome(s)
Psychological health following test result is assessed by MICRA Multi-dimensional impact of Cancer Risk Assessment (MICRA) scale at 7-days post-result, 6-months and 12 months.

Key secondary outcome(s))
1. Patient reported quality of life is assessed by EORTC QLQ C-30, OV28, EN-24, and EQ5D-5L questionnaires at baseline, post-result, 6-months, 12 months and annually
2. Anxiety and depression are assessed using the Hospital anxiety, depression scale (HADS) at baseline, post-result, 6-months, 12 months and annually
3. Cost effectiveness is reported using the Incremental cost effectiveness ratio per quality adjusted life years (ICER/QALY) at the end of the study
4. Germline and somatic BRCA1, BRCA2 detection rate is measured as the number of carriers /number of cases at the end of the study
5. Uptake is measured as the proportion of eligible EOC patients who accepted the offer of genetic testing at baseline
6. Patient satisfaction is assessed by the adapted genetic counselling satisfaction scale– measured post recruitment. A decision regret scale is used at 12 months.
7. PARP Inhibitor uptake is assessed by proportion of participants commenced on PARP inhibitors and reported at the end of the study

Completion date
04/05/2026

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Histological diagnosis of high-grade non-mucinous epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
Female

Key exclusion criteria
1. Women with non-epithelial ovarian cancer
2. Women with low grade or mucinous epithelial ovarian cancer
3. Unable to consent

Date of first enrolment
08/05/2017

Date of final enrolment
04/05/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St Bartholomew's Hospital
West Smithfield
London
United Kingdom
EC1a 7BE

Study participating centre
Royal London Hospital
Whitechapel Road
Whitechapel
London
United Kingdom
E1 1BB

Study participating centre
Queens Hospital
Romvalley Way
Romford
United Kingdom
RM70AG

Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
Barts and The London Charity

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from r.manchanda@qmul.ac.uk after publication of all results

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Other publications	Cohort study set within the recruitment to SIGNPOST	26/09/2023	27/09/2023	Yes	No