

BriTROC1 (The UK Translational Research in Ovarian Cancer Collaborative) - Sample collection study in recurrent high grade serous ovarian cancer (HGSOC)

Submission date 03/04/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/08/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/10/2023	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://www.cancerresearchuk.org/cancer-help/trials/a-study-help-understand-why-ovarian-cancer-can-come-back-or-continue-grow-after-treatment-britroc-1>

Contact information

Type(s)

Scientific

Contact name

Ms Liz-Anne Lewsley

Contact details

Beatson Oncology Centre
1053 Great Western Road
Glasgow
United Kingdom
G12 0YN
+44 141 301 7193
Liz-Anne.Lewsley@glasgow.ac.uk

Additional identifiers

Protocol serial number

13727

Study information

Scientific Title

BriTROCC1: Sample collection study to investigate the role of Homologous Recombination Deficiency in platinum sensitivity in recurrent high grade serous ovarian cancer

Acronym

BriTROCC1

Study objectives

The prevalence of patients with pre-existing Homologous Recombination Deficiency (HRD), including germline and somatic BRCA1 and BRCA2 mutation and epigenetic silencing, will be higher in platinum-sensitive relapsed populations than in platinum-resistant patients. Taken together with mutation analysis of other HRD genes, the overall proportion of HRD in platinum-sensitive relapsed high grade serous ovarian cancer (HGSOC) may be 50-60%.

Examination of HRD biomarkers in biopsy tissue at the time of relapse, together with comparison with original tissue and germline DNA, will identify markers of platinum response as well as novel mechanisms of resistance.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee East of England - Cambridge Central, 23/08/2012, ref: 12/EE/0349

Study design

Multi-centre non-randomised sample collection observational study

Primary study design

Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied

Topic: National Cancer Research Network; Subtopic: Gynaecological Cancer; Disease: Ovary /Fallopian tube

Interventions

Imaging guided (Ultrasound or CT), intra-operative or other suitable biopsies will be taken for research purposes from women who meet the eligibility criteria and who have been given written, informed consent. Blood will also be taken for storage of plasma and extraction of genomic DNA. Ascites will be collected if present and if drainage is deemed clinically indicated. For patients who consent, a further biopsy at subsequent relapse of disease will be taken. Patients will not be followed up within the context of this study.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

To obtain 300 fit-for purpose tumour biopsies from women with relapsed high grade serous ovarian cancer. Patients will have biopsy at baseline. This will take place at baseline after consent.

Key secondary outcome(s)

1. Assessment of mutations in HRD genes, BRCA1, BRCA2, RAD51C, RAD51D, BRIP1, in relapsed HGSOE samples by targeted sequencing
2. Comparison of allelic ratio of BRCA1 and BRCA2 in relapsed HGSOE and archival tumour samples taken at the time of diagnosis
3. Analysis of mutations in TP53 (positive control for high grade serous pathology), PTEN, APC, BRAF, KRAS, PIK3CA in relapsed HGSOE and archival tumour samples
4. Assessment of germline DNA mutations in BRCA1, BRCA2, RAD51C, RAD51D, BRIP1 in women with relapsed HGSOE
5. Assessment of methylation of BRCA1 and BRCA2 in relapsed HGSOE and archival tumour samples taken at the time of diagnosis

Timepoints: Baseline blood samples and pre chemotherapy (cycles 1 and 2, optional), archival tumour samples from original surgery.

Completion date

30/08/2018

Eligibility

Key inclusion criteria

1. Patients with recurrent histologically-proven high grade serous ovarian cancer, primary peritoneal carcinoma or fallopian tube cancer.
2. Patients may have received no more than two lines of prior chemotherapy
3. Availability of formalin-fixed, paraffin-embedded tissue taken at the time of original diagnosis of high grade serous ovarian cancer. This may be primary surgical debulking specimen OR core biopsy. For those with only a core biopsy from time of diagnosis, availability of specimen taken at interval debulking surgery is desirable, but not essential.
4. Patients must have disease deemed suitable for imaging-guided biopsy (ultrasound or CT) by an experienced radiologist.
5. Target Gender: Female, age \geq 18 years
6. Written informed consent.
7. Able to apply with study procedures.
8. Life expectancy $>$ 3 months
9. No contraindication to biopsy as appropriate

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. Ovarian, primary peritoneal or fallopian tube cancer of non-high grade serous pathology i.e. low grade serous, clear cell and endometrioid as well as carcinosarcoma/Malignant Mixed Mullerian Tumor (MMMT)
2. Borderline/low malignant potential tumours
3. Any non-epithelial ovarian malignancy
4. Patients with asymptomatic rising CA125 with no radiological evidence of recurrent ovarian cancer.
5. Original diagnosis of high grade serous cancer made on cytology only

Date of first enrolment

11/12/2012

Date of final enrolment

30/08/2017

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Beatson West of Scotland Cancer Centre

1053 Great Western Road

Glasgow

United Kingdom

G12 0YN

Sponsor information

Organisation

NHS Greater Glasgow & Clyde (UK)

ROR

<https://ror.org/05kdz4d87>

Funder(s)

Funder type

Charity

Funder Name

Ovarian Cancer Action (UK)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Acquisition of resistance	20/07/2023	20/10/2023	Yes	No
Results article	Safety and utility of image-guided research biopsies	13/03/2019	24/10/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes