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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

Registration date
27/08/2013

Overall study status
Completed

Last Edited
24/10/2023

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13727

Study information

Scientific Title
BriTROC1: Sample collection study to investigate the role of Homologous Recombination Deficiency in platinum sensitivity in recurrent high grade serous ovarian cancer

Acronym
BriTROC1

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 centre non-randomised sample collection observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Patient information sheet is available on the Cancer Research UK Clinical Trials Unit website: http://www.cactusonline.org.uk/rep/open_in_house_trials_yd7r63sh.pdf

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 measure
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.

Secondary outcome measures
1. Assessment of mutations in HRD genes, BRCA1, BRCA2, RAD51C, RAD51D, BRIP1, in relapsed HGSOC samples by targeted sequencing
2. Comparison of allelic ratio of BRCA1 and BRCA2 in relapsed HGSOC 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 HGSOC and archival tumour samples
4. Assessment of germline DNA mutations in BRCA1, BRCA2, RAD51C, RAD51D, BRIP1 in women with relapsed HGSOC
5. Assessment of methylation of BRCA1 and BRCA2 in relapsed HGSOC 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.

Overall study start date
11/12/2012

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 ≥ 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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
UK Sample Size: 300

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
Scotland

United Kingdom

Study participating centre
Beatson West of Scotland Cancer Centre
1053 Great Western Road
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Sponsor information

Organisation
NHS Greater Glasgow & Clyde (UK)

Sponsor details
Tennent Building
38 Church Street
Glasgow
Scotland
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G11 6NT

Sponsor type
Hospital/treatment centre

Website
http://www.nhsgg.org.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

Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Plain English results				No	Yes
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