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The experience of rucaparib in women with ovarian cancer

Submission date
22/02/2021

Recruitment status
Stopped

Registration date
30/06/2021

Overall study status
Stopped

Last Edited
29/04/2025

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A clinical trial showed that by taking rucaparib after a course of chemotherapy for recurrent ovarian cancer, it was possible on average to control the cancer for longer before it started to grow again and there was a longer time before women needed to have more chemotherapy. However, there were side effects associated with rucaparib and many women in the trial needed a break from treatment or a reduction in the dose of rucaparib.
There is information about the side effects experienced by women who participated in clinical trials of rucaparib. However, the population who enter clinical trials of new medicines can be different from the population treated in everyday practice. In particular, they are typically younger and have few other medical conditions. The purpose of this study is to assess the side effects experienced by women in everyday practice. These are often called "real-world studies". The researchers are investigating what (if any) side effects women experience, whether they need any breaks in treatment or if the dose of rucaparib needs to be reduced or stopped because of side effects. They will also look at the number of tablets that women actually manage to take of those that are prescribed. They will assess how effective rucaparib is in everyday practice compared to the results in the clinical trial. They will look at what treatment women receive after rucaparib and how effective that treatment is. They would also like to learn more about how the treatment impacts on everyday life. As well as some questionnaires that are frequently used in clinical trials, the researchers are using a newer questionnaire that investigates the impact of treatment on patients roles and responsibilities as a whole. They know that women understandably have concerns about their cancer getting worse. Sometimes these fears can be very difficult to manage and can affect quality of life. A recent study showed that a simple psychological support intervention might be able to help with this and the researchers would like to investigate the levels of fear of progression women experience when on rucaparib treatment to see if there is a need for this sort of supportive intervention.
The researchers want to explore the expectations women have of maintenance treatment after chemotherapy and will be using a questionnaire based on a survey that was previously performed in Europe. They would also like to know how women feel about their decision to have maintenance treatment after they complete chemotherapy. By collecting this information they hope to be able to give women more information in the future about what to expect from maintenance treatment to help them make a decision about having further treatment and also identify ways that they may be able to support them better.

The researchers are also collecting blood samples, before during and after treatment, to allow future research into why rucaparib works better for some people than others, and to look for markers in the blood that might predict who benefits and what changes in the cancer when it stops working.

Who can participate?
Women about to start rucaparib treatment as part of standard care for maintenance treatment recurrent ovarian cancer following platinum-based chemotherapy

What does the study involve?
At the first visit before starting rucaparib treatment the study doctors/nurse will ask about medical history, previous cancer treatment and current medications. The researchers will ask the participant to complete questionnaires and to give additional blood samples. At later visits (or telephone visits) the study doctor/nurses will ask about side effects or any missed treatment doses, and they will also ask about any new symptoms. A patient diary card will be given to participants to record when the participant has taken their medication or if they were unable to take the rucaparib for any reason. There will also be space to record any side effects.

What are the possible benefits and risks of participating?
There will not be a direct medical benefit to the participant from taking part in this study. Participation in the study may give additional information to doctors and patients in the future about the side effects and impact that having ovarian cancer and rucaparib treatment has on people's lives. This may help doctors to adapt treatment and give better support in the future. Analysis of blood samples may give information about who benefits the most from rucaparib and why tumors become resistant to it. Participating in this study will mean having additional blood tests taken which can cause some local pain and bruising. Completion of questionnaires will take additional time and some of the questions can be personal in nature.

Where is the study run from?
NHS Greater Glasgow & Clyde (UK)

When is the study starting and how long is it expected to run for?
October 2020 to September 2024

Who is funding the study?
Clovis Oncology (USA)

Who is the main contact?
Clare Dolan
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Contact information

Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
239749

Protocol serial number
GN20ON111

Study information

Scientific Title
Experience of rucaparib as maintenance treatment following platinum-based chemotherapy in relapsed ovarian cancer - a UK real-world study

Acronym
EXPLORER

Study objectives
It is hypothesized that the rate of adverse events (AEs), dose reductions, dose interruptions and discontinuations will be different in a real-world population compared to published trials. This combined with higher levels of co-morbidity may impact on outcomes and quality of life. In exploratory objectives, it is hypothesized that response to subsequent treatment may differ from historical controls who did not receive maintenance treatment so will investigate physician assessed radiological response rates to subsequent treatments. It is hypothesized that women will have clinically important scores on at least one European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-30) dimension or elements at baseline and that treatment or progression will have an effect on these scores for individuals. It is also hypothesized that treatment and disease progression will impact on women's ability to

maintain their usual roles and responsibilities, that women's expectations of the benefit of treatment may be unrealistic and some women may experience decisional regret. In addition, some women will score highly on fear of progression scales and high scores will correlate with poor scores on other quality of life scales.

The time from completion of last platinum to subsequent progression is the best predictor of response to further platinum-based treatment in women with relapsed disease. However, it is not known if or how maintenance therapy will affect the relationship between platinum-free interval and response to further platinum. This is very important information for women who require treatment after progression on a PARP inhibitor. Therefore, in the study the researchers will collect the type of next treatment, the response as assessed by physician assessed radiological criteria and the time to next subsequent treatment or death. This will be compared with historical data from cohorts that did not receive maintenance poly ADP ribose polymerase (PARP) inhibitors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/02/2021, West of Scotland REC 4 (Dykebar Hospital, Ward 11, Ground Floor, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 314 0213; Westofscotland.researchethicscommittee4@ggc.scot.nhs.uk), REC ref: 21/WS/0032

Primary study design
Observational

Study design
Observational trial with translation sample collection

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ovarian cancer

Interventions
Participants will receive treatment with rucaparib 600 mg BD until progression or unacceptable toxicity. No additional monitoring or investigations for safety or efficacy over standard practice will be performed but this data will be collected within the study. Participants will be assessed as per standard of care prior to each new cycle of treatment – including assessment of adverse events, blood results, physical examination and vital signs which have been recorded as part of standard of care will be recorded. Any dose reductions, interruptions or delays in treatment will also be recorded. The study doctor will be asked to record whether there is any evidence of progression of the cancer by clinical criteria, rise in blood markers (CA125) or on a CT scan if performed as part of routine care.

Participants will be in the study for between 12-36 months depending on what point during the recruitment period they join the study. The post-progression visit will occur 1-2 months after progression of their cancer or end of treatment whichever is later. After this follow up data will be collected remotely without additional visits.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Rucaparib

Primary outcome(s)
1. Adverse events measured by CTC v05 at all study visits: baseline, at the start of every treatment cycle on treatment (initially every 4 weeks), at progression of the cancer or end of treatment and 1 to 2 months post progression of the cancer
2. Proportion of patients who require one or more dose reductions due to toxicity, defined as the number of patients who are prescribed a dose lower than the licensed starting dose at some points in their treatment divided by the total number of patients. Doses prescribed will be determined from prescribing records at the start of every treatment cycle (initially every 4 weeks)
3. Proportion of patients who require one or more dose interruptions due to toxicity, defined as the number of patients who require a dose interruption at some point in their treatment divided by the total number of patients. Dose interruptions will be determined from prescribing records at the start of every treatment cycle (initially every 4 weeks)

Key secondary outcome(s)
1. Progression-free survival, defined as the time from start of rucaparib to date of progression by radiological criteria (physician assessed)
2. Progression-free survival (CA125), defined as the time from the start of rucaparib to date of progression by GCIG CA125 criteria
3. Time to first subsequent therapy, defined as the time from the start of rucaparib to first day of subsequent therapy
4. Overall survival, defined as the time from the start of rucaparib to date of death. Patients will be censored at last known follow up
5. Type of subsequent therapy name and schedule of subsequent systemic therapy derived from prescribing records, dose and schedule of any radiotherapy, type and date of surgical procedure determined from clinical records, assessed every 3 months after the end of treatment /progression of the cancer, whichever is later, until the end of the study
6. Time to second subsequent therapy, defined as the time from the start of rucaparib to the first day of second subsequent therapy
7. Cancer-related quality of life measured using EORTS QLQ C30 at cycle 1 day 1, cycle 2 day 1, cycle 4 day 1, cycle 7 day 1, end of treatment, at progression and post progression
8. General health-related quality of life measured using EQ-5D at cycle 1 day 1, cycle 2 day 1, cycle 4 day 1, cycle 7 day 1, end of treatment, at progression and post progression

Completion date
30/09/2024

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Women where a decision has been made to start rucaparib as part of standard care for maintenance treatment recurrent ovarian cancer following to platinum based chemotherapy and they have not yet started treatment
2. Written informed consent
3. Ability and willingness to complete questionnaires in English
4. Meet institutional criteria for treatment in standard practice

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
34

Key exclusion criteria
1. Prior treatment with a poly ADP ribose polymerase (PARP) inhibitor
2. Current treatment with another maintenance therapy for ovarian cancer
3. Participation in another trial of an investigational medicinal product (IMP) (participation in another observational or sample collection trial may be possible if both Sponsors agree and the burden on the patient is acceptable)

Date of first enrolment
01/06/2021

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre

Beatson West of Scotland Cancer Centre
1053 Great Western Road
Glasgow
United Kingdom
G12 0YN

Study participating centre
The Christie Research Division
The Oglesby Cancer Research Building
555 Wilmslow Road
Manchester
United Kingdom
M20 4GJ

Study participating centre
Clatterbridge Cancer Centre
65 Pemproke Place
Liverpool
United Kingdom
L7 8YA

Study participating centre
Guys & St Thomas Hospital
Cancer Centre Floor C1
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
South West Wales Cancer Institute
SIngleton Hospital
Sketty Lane
Sketty
Swansea
United Kingdom
SA2 8QA

Study participating centre
Worcestershire Royal Hospital
Charles Hastings Way

Worcester
United Kingdom
WR5 1DD

Study participating centre
Velindre Cancer Centre
Velindre Road
Whitchurch
Cardiff
United Kingdom
CF14 2TL

Sponsor information

Organisation
NHS Greater Glasgow and Clyde

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Industry

Funder Name
Clovis Oncology

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

Data is being collected via electronic case report form (eCRF) hosted by the Robertson Centre for Biostatistics (RCB) at Glasgow University. Anonymised data entered into the eCRF will be managed and stored by the RCB in line with the detailed Data Management Plan, which will be developed in line with approved templates and reviewed regularly. All members of the study team will adhere to the data management plan and well established SOPs. All anonymised study data will be retained for 10 years following the end of the study. Glasgow Clinical Trials Unit (of which RCB is a part) will serve as custodian of the data generated by this study. After primary analysis and publication, data will be available for sharing for ethically approved projects as per patient consent. Requests for data should be made to the Sponsor and will be considered on a case by case basis with input from the Study Management Group.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			05/06/2024	No	No
HRA research summary			28/06/2023	No	No