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Rucaparib window of opportunity study

Submission date 14/05/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 14/05/2015	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 16/06/2022	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-of-rucaparib-for-triple-negative-breast-cancer-or-breast-cancer-with-brca-gene-faults-rio

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
2014-003319-12

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
18804

Study information

Scientific Title
Window study of the PARP inhibitor rucaparib in patients with primary triple negative or BRCA1 /2 related breast cancer (RIO)

Acronym
RIO

Study objectives
The aim of the RIO trial is to determine the percentage of primary TNBCs or BRCA1/2 related breast cancers that display sensitivity to the PARP inhibitor rucaparib by measuring change in tumour cells multiplying after 12-14 days of rucaparib treatment. RIO will also aim to identify biomarkers that can identify patient groups sensitive to this medication to allow further analysis of rucaparib in these cancers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/LO/2181; First MREC approval date 30/01/2015

Study design
Non-randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Cancer; Subtopic: Breast Cancer; Disease: Breast

Interventions
Rucaparib, All patients entering the trial will recieve rucaparib (600mg, twice daily) for 12-14 days. Following completion of rucaparib treatment patients will proceed to standard care. Follow Up Length: 1 month(s); Study Entry : Registration only

Intervention Type
Other

Phase
Phase II

Primary outcome(s)
Ki67 response from baseline to end of rucaparib in patients with sporadic triple negative cancers; Timepoint(s): Response to rucaparib is defined as 50% or greater fall in Ki67 from baseline.

Key secondary outcome(s))
N/A

Completion date
18/12/2016

Eligibility

Key inclusion criteria
1. Male or female patients aged 16 years or older
2. Histologically proven carcinoma of the breast amenable to biopsy
3. Either breast tumour size 2cm or greater OR <2cm tumour with cytologically or histologically confirmed axillary lymph node metastases
4. WHO performance status 0, 1 or 2
5. Either:
5.1. Primary sporadic triple negative breast cancer defined as oestrogen receptor (ER) negative, progesterone receptor (PgR) negative (as defined by Allred score 0/8 or 2/8 or stain in <1% of cancer cells) and HER2 negative (immunohistochemistry 0/1+ or negative in situ hybridization) as determined by local laboratory. Patients should not be known to have a germline pathogenic BRCA1 or BRCA2 mutation at study entry.
OR
5.2. Primary BRCA1/2 related breast cancer as defined by a breast carcinoma of any phenotype (ER +ve or –ve, PgR +ve or –ve, HER2 +ve or –ve) occurring in a patient with a known germline pathogenic BRCA1 or BRCA2 mutation
6. Adequate organ function confirmed by the following laboratory values obtained within 14 days prior to the first dose of rucaparib:
6.1. Bone marrow function: ANC ≥ 1.5 x 109/L; Platelets >100×109/L; Hemoglobin ≥9 g/dL
6.2. Hepatic function: Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) ≤2.5 x upper limit of normal (ULN); Bilirubin ≤1.5 x ULN
6.3. Renal function: serum creatinine ≤1.5 x ULN
7. Patients or patients with partners of childbearing potential must use adequate contraception during trial participation. A negative pregnancy test is required by female patients prior to the of therapy. Female patients will be deemed not of childbearing potential if they are postmenopausal (aged >50 and amenorrhoeic for at least 12 months) or have had irreversible surgical sterilization
8. ER negative patients may enter the trial whether or not they have taken hormone replacement therapy (HRT) or the oral contraceptive pill (OCP) within the last four weeks. ER positive patients on HRT or the OCP must either continue HRT/OCP for the duration of the study or must not have taken HRT/OCP within the last four weeks before trial entry. The possible benefits and risks of continuing HRT/OCP must be discussed with the patient
9. Patients with primary breast cancer and evidence of metastatic disease on first presentation are eligible providing they have not had prior treatment
10. Patients must be willing and able to provide informed consent and to comply with all study procedures (including providing additional tumour biopsies for research purposes) and visit schedules

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Any prior or concurrent treatment for the current diagnosis of breast cancer
2. Any anti-cancer treatment within the previous 12 months for prior diagnosis of cancer other than for basal cell carcinoma of the skin or cervical carcinoma in situ
3. Prior history of ipsilateral breast cancer within the previous 5 years
4. Impaired cardiac function or clinically significant cardiac disease, including any of the following:
4.1. Unstable angina pectoris =3 months prior to first scheduled dose of rucaparib
4.2. Acute myocardial infarction =3 months prior to first scheduled dose of rucaparib
5. Presence of any systemic illness incompatible with participation in the clinical trial or inability to provide written informed consent
6. Treatment with an unlicensed or investigational drug within 4 weeks prior to trial entry
7. Prior treatment with any PARP inhibitor, including oral or intravenous rucaparib
8. Administration of strong CYP1A2 and CYP3A4 inhibitors or inducers (as detailed in Appendix 1) =7 days prior to first scheduled dose of rucaparib
9. Females who are pregnant or breastfeeding

Date of first enrolment
18/06/2015

Date of final enrolment
18/12/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Institute of Cancer Research
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Sponsor information

Organisation
ICR Clinical Trials and Statistics Unit (ICR-CTSU)

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Industry

Funder Name
Clovis Oncology inc

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		20/06/2020	16/06/2022	No	No
HRA research summary			28/06/2023	No	No