

# Rucaparib window of opportunity study

<b>Submission date</b> 14/05/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 14/05/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/06/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> 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

### Contact name

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### Contact details

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## Additional identifiers

### EudraCT/CTIS number

2014-003319-12

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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

## Secondary study design

Non randomised study

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

## Health condition(s) or problem(s) studied

Topic: Cancer; Subtopic: Breast Cancer; Disease: Breast

## Interventions

Rucaparib, All patients entering the trial will receive 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 measure**

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.

## **Secondary outcome measures**

N/A

## **Overall study start date**

18/06/2015

## **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  $\geq 1.5 \times 10^9/L$ ; Platelets  $>100 \times 10^9/L$ ; Hemoglobin  $\geq 9$  g/dL
  - 6.2. Hepatic function: Aspartate aminotransferase (AST) and alanine aminotransferase (ALT)  $\leq 2.5$  x upper limit of normal (ULN); Bilirubin  $\leq 1.5$  x ULN
  - 6.3. Renal function: serum creatinine  $\leq 1.5$  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

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

Planned Sample Size: 91; UK Sample Size: 91

### **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**

England

United Kingdom

**Study participating centre**

**The Institute of Cancer Research**

ICR-CTSU

Division of Clinical Studies

15 Cotswold Road

Belmont

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## **Sponsor information**

**Organisation**

ICR Clinical Trials and Statistics Unit (ICR-CTSU)

**Sponsor details**

Institute of Cancer Research

Surrey Clinical Trials & Statistics Unit (ICR-CTSU)

Section of Clinical Trials Brookes

Lawley Building

15 Cotswold Road

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England

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**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/043jzw605>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Clovis Oncology inc

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## 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?
<a href="#">Basic results</a>		20/06/2020	16/06/2022	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No