

# CORAL: Cancer of the OvaRy Abiraterone trial

<b>Submission date</b> 03/04/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/05/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/08/2022	<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-looking-at-abiraterone-for-women-with-ovarian-primary-peritoneal-or-fallopian-tube-cancer-coral>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

2013-000293-29

### Protocol serial number

ICR-CTSU/2012/10038

## Study information

**Scientific Title**

A phase II study of abiraterone in patients with recurrent ovarian, fallopian tube, or primary peritoneal cancer

**Acronym**

CORAL

**Study objectives**

The study hypothesis is that abiraterone will show clinical activity in patients with epithelial ovarian cancer (EOC).

We also aim to identify biomarkers of abiraterone sensitivity in EOC and evaluate the molecular impact of abiraterone.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee London – Westminster, 22/10/2013, REC ref: 13/LO/1599

**Study design**

Prospective open-label non-randomised two-stage phase II clinical trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Patients with epithelial ovarian cancer (including fallopian tube and primary peritoneal) that has relapsed within 12 months of last treatment.

**Interventions**

Evaluating the efficacy of abiraterone in patients with ovarian, including fallopian tube and primary peritoneal, cancer.

Oral abiraterone 1000mg (4x250mg) plus 5mg prednisone/prednisolone once a day  
Patients will continue on trial treatment until disease progression. We anticipate the study running for around 3 years, from first patient recruited to last patient last data capture

**Details of co-sponsor:**

Royal Marsden NHS Foundation Trust  
R&D Office  
Royal Marsden Hospital  
Downs Road  
Sutton  
United Kingdom

**Intervention Type**

Drug

## Phase

Phase II

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

Abiraterone

## Primary outcome(s)

The primary objective of this study is to determine whether abiraterone has clinical activity (objective response rate assessed by imaging and/or CA125 tumour marker changes in the blood) in patients with epithelial ovarian cancer.

## Key secondary outcome(s)

1. The proportion of patients with objective response according to RECIST
  2. The proportion of patients with objective response according to GCIG (CA125)
  3. Clinical benefit rate according to RECIST/GCIG criteria at 12 weeks
  4. Progression Free Survival (PFS)
  5. 6-month PFS
  6. Time to Progression (TTP)
  7. Overall survival (OS)
  8. Toxicity according to CTCAE version 4.0
- We will also explore the molecular impact of abiraterone and attempt to identify biomarkers of abiraterone sensitivity in epithelial ovarian cancer.

## Completion date

14/07/2016

## Eligibility

### Key inclusion criteria

1. Histologically or cytologically confirmed epithelial ovarian, fallopian tube (FT) or primary peritoneal (PP) cancer and have progressed (radiological or CA125 criteria) within 12 months of last systemic anti-cancer therapy
  2. Life expectancy of at least 12 weeks
  3. Post-menopausal defined as:
    - 3.1. Aged  $\geq 18$  years having had bilateral salpingo-oophorectomy (BSO)
    - 3.2. Aged  $\geq 45$  years with intact uterus and amenorrhoeic for at least 12 months
    - 3.3. FSH  $>40$  U/L in patients who have had a hysterectomy and ovaries are intact (i.e. not had bilateral oophorectomy)
- Documented evidence is required for patients who have undergone irreversible surgical sterilisation by hysterectomy, bilateral oophorectomy or bilateral salpingectomy
4. ECOG performance status of 0-2
  5. No prior hormone therapy (e.g. tamoxifen, aromatase inhibitor, progestogens, anti-androgens)
  6. At least one line of prior platinum-based chemotherapy
  7. Measurable or evaluable disease (if not measurable by RECIST v1.1 criteria, patients must be evaluable by GCIG CA125 criteria). See Appendix 2
  8. Archival primary tumour tissue (FFPE or 8-10 unstained slides) must be available. Otherwise, a biopsy must be carried out to obtain sufficient tissue for histological assessment
  9. No evidence of pre-existing uncontrolled hypertension as documented by two baseline blood pressure readings taken at least an hour apart. The baseline systolic blood pressure readings must be  $<160$  and the baseline diastolic blood pressure readings must be  $<95$  mmHg. Patients whose hypertension is controlled by antihypertensive therapies are eligible

10. Haematological and biochemical indices within acceptable specified ranges
11. Aged 18 years or over
12. Written (signed and dated) informed consent and be capable of co-operating with treatment and follow-up

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**Total final enrolment**

42

**Key exclusion criteria**

1. Tumours of mucinous, clear cell, malignant mixed mesodermal (MMMT) or non-epithelial ovarian cancers (e.g. Brenner tumours, Sex-cord tumours)
2. Radiotherapy (except for palliative reasons) or chemotherapy within the preceding three weeks (four weeks for investigational agent or within five half-lives of the investigational agent, whichever is longer)
3. Persistent grade 2 or greater toxicities from any cause except for alopecia or grade 2 peripheral neuropathy
4. Known leptomeningeal involvement or brain metastases
5. Clinical and/or biochemical evidence of hyperaldosteronism or hypopituitarism
6. Unresolved bowel obstruction
7. Major surgery within four weeks prior to entry to the study or minor surgery within two weeks of entry into the study and from which the patient has not yet recovered
8. Treatment with warfarin. Patients on warfarin for DVT/PE can be converted to LMWH at least one week prior to commencement of trial treatment
9. At high medical risk, as deemed by the Principal Investigator, because of non-malignant systemic disease including active uncontrolled infection
10. Known to be serologically positive for hepatitis B and/or hepatitis C
11. Active or uncontrolled autoimmune disease that may require corticosteroid therapy
12. History of clinically significant heart disease, e.g. myocardial infarction or arterial thrombotic event within six months, severe or unstable angina, or New York Heart Association Class III or IV heart disease
13. Systolic blood pressure >160 mm Hg and diastolic blood pressure >95 mm Hg documented on at least two different occasions  
[Note: Hypertension controlled by antihypertensive therapy is permitted].
14. Any other active malignancy requiring treatment/or whose prognosis will prevent readout from trial endpoints
15. Patients for whom treatment with prednisone or prednisolone is contraindicated

16. Patients participating in or planning to participate in another interventional clinical trial.  
Participation in an observational trial is acceptable

17. Any other condition which, in the Investigators opinion, would not make the patient a good candidate for the clinical trial

**Date of first enrolment**

15/07/2013

**Date of final enrolment**

31/12/2015

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**The Royal Marsden NHS Foundation Trust**

London

United Kingdom

SM2 5PT

## **Sponsor information**

**Organisation**

The Institute of Cancer Research (UK)

**ROR**

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

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Study drug and funding provided by Janssen-Cilag

## Funder Name

CORAL has received endorsement from Cancer Research UK (CRUK) (ref: A16037)

## 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?
<a href="#">Results article</a>		29/12/2020	16/04/2021	Yes	No
<a href="#">Abstract results</a>	results presented at the European Society of Medical Oncology (ESMO) conference	01/10/2016	26/10/2020	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Plain English results</a>			09/08/2022	No	Yes