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CORAL: Cancer of the OvaRy Abiraterone trial

Submission date	Recruitment status	[X] Prospectively registered
03/04/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/05/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/08/2022	Cancer	

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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Additional identifiers

EudraCT/CTIS number
2013-000293-29

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Please use the contact information provided to request a Patient Information Sheet.

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 measure
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.

Secondary outcome measures
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.

Overall study start date
15/07/2013

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 ≥ 18 years having had bilateral salpingo-oophorectomy (BSO)
3.2. Aged ≥ 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 specifed 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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
47

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
England

United Kingdom

Study participating centre
The Royal Marsden NHS Foundation Trust
London
United Kingdom
SM2 5PT

Sponsor information

Organisation

The Institute of Cancer Research (UK)

Sponsor details
123 Old Brompton Road
London
United Kingdom
SW7 3RP

Sponsor type
Research organisation

Website
http://www.icr.ac.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

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

	Date	Date	Peer	Patient-

Output type	Details	created	added	reviewed?	facing?
Abstract results	results presented at the European Society of Medical Oncology (ESMO) conference	01/10/2016	26/10/2020	No	No
Results article		29/12/2020	16/04/2021	Yes	No
Plain English results			09/08/2022	No	Yes
HRA research summary			28/06/2023	No	No