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Saracatinib (AZD0530) plus weekly paclitaxel in platinum-resistant ovarian, fallopian tube or primary peritoneal cancer

Submission date	Recruitment status	[X] Prospectively registered
29/10/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/10/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/03/2022	Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-paclitaxel-saracatinib-ovarian-cancer-fallopian-tube-cancer-primary-peritoneal-cancer-sapproc

Study website
http://www.ctc.ucl.ac.uk/TrialGroup.aspx?TrialGroupID=3

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2009-017171-13

IRAS number

ClinicalTrials.gov number
NCT01196741

Secondary identifying numbers
8430

Study information

Scientific Title
A randomised placebo-controlled trial of saracatinib (AZD0530) plus weekly paclitaxel in platinum-resistant ovarian, fallopian tube or primary peritoneal cancer

Acronym
SaPPrOC

Study objectives
This is a randomised, placebo-controlled double-blind trial. The overall aim is to investigate whether the addition of the Src inhibitor saracatinib (AZD0530) to weekly paclitaxel improves efficacy, compared with paclitaxel plus placebo, in patients with relapsed platinum-resistant ovarian cancer. The trial will also determine toxicity and ascertain whether the combination of paclitaxel plus saracatinib should proceed to a phase III trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Coventry & Warwickshire Research Ethics Committee, 04/08/2010, ref: 10/H1211/26

Study design
Multicentre randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Gynaecological Cancer; Disease: Ovary

Interventions
Paclitaxel 80 mg/m2 (IV) to be given in 'cycles'. Each cycle will be 8 weeks of treatment, consisting of six weekly administrations of paclitaxel 80 mg/m2 followed by 2 weeks rest. Patients will receive four cycles to begin with. If there is evidence of ongoing response after four cycles, three further cycles will be given, unless there is dose-limiting toxicity or the patient requests to discontinue treatment. If best response is stable disease after four cycles, treatment should be discontinued but may continue at the discretion of the Investigator. The maximum chemotherapy treatment period will be 56 weeks.

Saracatinib (AZD0530). Patients will receive 175 mg/matched placebo daily. Administration will begin 1 week prior to commencement of paclitaxel chemotherapy, and will continue until the patient's disease progresses/relapses. Combined with chemotherapy, the maximum treatment period of saracatinib/placebo will be 57 weeks.

Patients who progress/relapse during trial treatment will be taken off study and not followed up. Patients who do not relapse/progress during trial treatment will be followed up and offered saracatinib/placebo monotherapy. These patients will be followed up 6 weekly for 2 years or until progression, whichever is the sooner.

Intervention Type
Drug

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
Saracatinib (AZD0530), paclitaxel

Primary outcome measure
Six-month progression-free survival (PFS), based on combined RECIST v1.1/GCIG CA125 criteria

Secondary outcome measures
1. Duration of response
2. Health Economics and Quality of Life outcomes based on FACT-O and EQ5D
3. Investigator Assessed PFS based on RECIST v1.1
4. Investigator Assessed Time to Progression
5. Objective Response Rate based on Investigator assessment using GCIG CA125 criteria and RECIST v1.1
6. Overall survival rate at 2 years
7. Safety and tolerability (toxicity)
8. Time to Progression based on RECIST v1.1

Overall study start date
01/11/2010

Completion date
01/05/2012

Eligibility

Key inclusion criteria
1. Confirmed relapsed ovarian, fallopian tube or primary peritoneal cancer AND patients who have relapsed in the platinum-resistant (progression must not be based on CA125 alone) time-frame, i.e. have progressed within 6 months of platinum therapy
2. All patients must have formalin-fixed paraffin-embedded (FFPE) tissue available for translational research: this tissue may be tissue taken at original diagnosis
3. Patients need not have received prior taxane; if patients have received prior taxane, the interval since treatment must be known. Patients will be stratified as less than 6 months OR at least 6 months taxane interval/no prior taxane.
4. Patients will generally have received at least two lines of prior chemotherapy, but may enter if they have relapsed within 6 months of first-line therapy. Patients may have received prior liposomal doxorubicin, although this is NOT a requirement. The treatment immediately prior to study entry need not be platinum-based.
5. Measurable or evaluable disease (if not measurable by Response Evaluation Criteria in Solid Tumours version 1.1 [RECIST v1.1] criteria, must be evaluable by CA125 [GCIG criteria])
6. Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0 - 2
7. Adequate haematological and biochemical function as follows:
7.1. Granulocyte count greater than 1.5 x 10^9/l
7.2. Platelet count greater than 100 x 10^9/l
7.3. Haemoglobin (Hb) greater than 9.0 g/dl
7.4. Serum creatinine less than 1.5 x upper limit of normal (ULN)
7.5. Bilirubin less than 1.5 x ULN. In cases of known Gilbert's syndrome, bilirubin less than 2 x ULN is allowed
7.6. Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) less than 2.5 x ULN
7.7. Alkaline phosphatase (ALP) less than 5 x ULN
7.8. Prothrombin and activated partial thromboplastin times less than 1.5 x ULN
8. Willingness to consent to take part in Level 1 of the translational sub-study, as per section 19.0 of the protocol (this is NOT optional)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned sample size: 102; UK sample size: 102

Total final enrolment
107

Key exclusion criteria
1. Prior administration of weekly paclitaxel
2. Tumours of malignant mixed mesodermal (MMMT) or mucinous types
3. Unresolved bowel obstruction
4. Chemotherapy within the preceding 3 weeks
5. Radiotherapy within the preceding 3 weeks
6. Treatment with any investigational agent within the preceding 4 weeks or within 5 half-lives

of the investigational agent, whichever is longer
7. Known leptomeningeal involvement or intracranial disease
8. Evidence of interstitial lung disease (bilateral, diffuse, parenchymal lung disease)
9. Resting electrocardiogram (ECG) with measurable QTc interval of greater than 480 msec at two or more time points within a 24-hour period
10. Pregnant or lactating females
11. Fertile women of childbearing potential not willing to use adequate contraception for the duration of trial treatment and for at least 30 days after the last administration of saracatinib +/- paclitaxel
12. Inability or unwillingness to give informed consent
13. Ongoing active infection or a documented history of human immunodeficiency virus (HIV) infection, hepatitis B or C
14. Concurrent congestive heart failure or prior history of New York Heart Association (NYHA) class III/IV cardiac disease
15. Concurrent autoimmune disorder, e.g. systemic lupus or any demyelinating disease
16. Use of immunosuppressive therapy or corticosteroids taken within the 4 weeks prior to study entry and during the treatment period

Date of first enrolment
01/11/2010

Date of final enrolment
01/05/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cancer Research UK & UCL Cancer Trials Centre
London
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Sponsor information

Organisation
University College London (UCL) (UK)

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Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
AstraZeneca

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
Cancer Research UK- Clinical Trials Advisory and Awards Committee (CTAAC) grant (ref: C9423 /A11569)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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?
Basic results				No	No
Results article	results	01/10/2014		Yes	No
Plain English results			31/03/2022	No	Yes
HRA research summary			28/06/2023	No	No