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Study to see if GSK2110183 with chemotherapy can treat ovarian cancer

Submission date	Recruitment status	[_] Prospectively registered
16/01/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/01/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/04/2021	Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-cell-changes-ovarian-cancer-aktres

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01653912

Clinical Trials Information System (CTIS)
2012-002483-27

Protocol serial number
13614, PKB116611

Study information

Scientific Title
AKTRES study: A Biologic Study of the early effects and determinants of AKT inhibition using GSK2110183 alongside chemotherapy in patients with platinum RESistant adenocarcinoma of the ovary

Acronym
AKTRES

Study objectives
Activation of the AKT signalling pathway in ovarian cancer cells causes chemotherapy resistance. An AKT inhibitor, given alongside chemotherapy, could potentially reverse this resistance and enable chemotherapy to be effective once again. This study is designed for women whose ovarian cancer has relapsed within 6 months of receiving carboplatin or cisplatin-containing chemotherapy and who are receiving an AKT inhibitor given alongside 3 weekly carboplatin and paclitaxel in the PKB116611 trial. Participants in the AKTRES study undergo a maximum of two biopsies from their tumour and some additional blood tests. The aims of the study are to better understand the how chemotherapy-resistant cancer cells are affected by AKT inhibitors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Hampstead, 07/11/2012, ref. 12/LO/1174

Study design
Non-randomised; Interventional; Design type: Process of Care, Treatment

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Blood sampling, [3 x 10 ml whole blood collected in greentopped (heparinised) tube] will be collected at baseline (within 14 days prior to first dose), on day 1 (immediately preceding chemotherapy), day 8 and day 15 of cycle 1 only. Blood sampling will subsequently be performed at day 1 only of subsequent chemotherapy treatment cycles and thereafter 3 weekly for those on maintenance GSK2110183 alone. A final 3 x 10 ml blood sample will be taken at end of study visit.
Coagulation profile, will be collected immediately prior to the first biopsy during the screening period and postcycle 1 biopsy on day 22. This is in addition to the screening coagulation blood test required for PKB116611 study.
Collection of ascites: If patients are undergoing ascitic or pleural drainage for symptom relief

prior to, or during, this study a sample of ascites (or pleural effusion) can be taken and stored. The preferred times for collection are during screening, day 22 and at study completion, but additional/alternative collections can be obtained at the investigators discretion.
Tumour Biopsy: A tumour biopsy performed under image guidance within 14 days prior to first dose. Three tumour cores will be taken, two will be fresh frozen and one will be formalin fixed. Following one complete treatment cycle (day 22), =3 days prior to starting cycle 2 day 1, a second tumour biopsy will be performed under image guidance. Again, three tumour cores will be taken, two will be fresh frozen and one will be formalin fixed. Patients can decline the second biopsy if they wish to.

Intervention Type
Drug

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
GSK2110183 (afurasertib)

Primary outcome(s)
Overall Response, CA125 response and Progression free survival measured by ELISA detected decrease in phosphorylated PRAS40 (as ratio of total PRAS40) and increase in pAKT S473

Key secondary outcome(s)
Not provided at time of registration

Completion date
04/12/2014

Eligibility

Key inclusion criteria
1. Female at least 18 years of age at the time of signing the informed consent form
2. Capable of giving written informed consent
3. Having measurable tumour tissue and Platinum-resistant ovarian cancer as defined as radiological evidence of disease progression within 6 months of completion of platinum-containing chemotherapy
4. Tumour tissue measuring >2cm long axis amenable to direct biopsy or biopsy via image-guidance

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
Female

Total final enrolment
59

Key exclusion criteria
Concurrent medication with warfarin or low molecular weight heparin (heparin use is acceptable if it has been discontinued for 2 days preceding biopsy)

Date of first enrolment
10/12/2012

Date of final enrolment
04/12/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hammersmith Hospital
London
United Kingdom
W12 0HS

Sponsor information

Organisation
Imperial College of Science, Technology and Medicine (UK)

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Charity

Funder Name
Ovarian Cancer Action (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2019	14/04/2021	Yes	No
Basic results				No	No
Basic results				No	No