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Study of a marker of angiogenic response to combination therapy with pazopanib, and weekly paclitaxel in platinum resistant ovarian cancer

Submission date 10/08/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 10/08/2011	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/03/2019	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-see-how-well-pet-scans-pick-up-blood-supply-changes-ovarian-cancer-treated-pazopanib-paclitaxel-pazpet-1

Contact information

Type(s)
Scientific

Contact name
Dr Rohini Sharma

Contact details
MRC Cyclotron Unit
Hammersmith Hospital
Du Cane Road
London
United Kingdom
W12 0HS

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01608009

Secondary identifying numbers
9301, CRO1627

Study information

Scientific Title
Phase 1b exploratory study of [18F]AH111585-PET as a marker of angiogenic response to combination therapy with the pan-VEGF inhibitor, pazopanib, and weekly paclitaxel in platinum resistant ovarian cancer

Acronym
PAZPET-1

Study objectives
Pazopanib is an unlicensed drug in tablet form that mainly targets the blood vessels supplying tumours and works best alongside other chemotherapy drugs. It attacks the protein on the blood vessels that is thought to be responsible for the resistance to chemotherapy. Paclitaxel is a licensed type of chemotherapy that is used to treat cancers and has been shown not only to shrink cancers but also target the abnormal blood vessels that supply nutrients to the cancer. The study uses PET (Positron Emission Tomography) scanner along with a very small amount of radioactive substance called "Tracer". As the blood vessels that supply nutrients to the tumour are destroyed there will be less of the tracer seen around the tumour. The PET scanner can detect that and gives us an idea about what is happening to the blood vessels that supply nutrients to the tumour. We collect blood and biopsy samples from patients and they will later be tested to gain more of an understanding about the way that the chemotherapy works and how good the scans are at detecting the chemotherapy changes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
ref: 10/S0801/36

Study design
Non-randomised, interventional study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Gynaecological cancer, ovarian cancer

Interventions
fluciclatide-PET, PET imaging technique with novel tracer

Intervention Type
Drug

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
Paclitaxel, pazopanib

Primary outcome measure
Response to therapy

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/11/2011

Completion date
01/11/2012

Eligibility

Key inclusion criteria
1. Age over 18 years
2. Diagnosis of relapsed ovarian cancer
3. Responded to at least on one line of prior platinum based therapy
4. Relapsed within platinum resistant interval (=6months)
5. Eastern Cooperative Oncology Group (ECOG) performance status of <2
6. Measurable disease defined as a lesion that can be accurately measured in at least one dimension with the longest diameter = 25mm using conventional techniques
7. Adequate organ system function
8. Female participants only

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Female

Target number of participants
Planned Sample Size: 17; UK Sample Size: 17

Key exclusion criteria
1. Poorly controlled hypertension [defined as systolic blood pressure (SBP) of =140 mmHg or diastolic blood pressure (DBP) of = 90mmHg].
Note: Initiation or adjustment of antihypertensive medication(s) is permitted prior to study entry. BP must be re-assessed on two occasions that are separated by a minimum of 1 hour; on each of these occasions, the mean (of 3 readings) SBP / DBP values from each BP assessment must be <140/90 mmHg in order for a subject to be eligible for the study.
2. Treatment with any of the following anti-cancer therapies:
2.1. Radiation therapy 28 days prior to the first dose of pazopanib OR
2.2. Surgery or tumor embolization within 14 days prior to the first dose of pazopanib OR
2.3. Chemotherapy, immunotherapy, biologic therapy, investigational therapy or hormonal therapy within 14 days or five half-lives of a drug (whichever is longer) prior to the first dose of pazopanib
3. Treatment with anti-angiogenic therapy
4. Presence of gross ascites
5. Clinically significant peripheral neuropathy
6. Females of childbearing potential who are unwilling to avoid pregnancy, for the duration of the study

Date of first enrolment
01/11/2011

Date of final enrolment
01/11/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Cyclotron Unit
London
United Kingdom
W12 0HS

Sponsor information

Organisation

Imperial College London (UK)

Sponsor details
School of Medicine
Hammersmith Hospital
Du Cane Road
London
England
United Kingdom
W12 0HS

Sponsor type
University/education

Website
http://www3.imperial.ac.uk/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Industry

Funder Name
GSK (UK)

Funder Name
Higher Education Funding Council for England

Alternative Name(s)
HEFCE

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

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

IPD sharing plan summary
Not provided at time of registration