

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	☒ 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

ClinicalTrials.gov (NCT)

NCT01608009

Protocol serial number

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

Primary study design

Interventional

Study design

Non-randomised, interventional study

Study type(s)

Treatment

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(s)

Response to therapy

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key exclusion criteria

1. Poorly controlled hypertension [defined as systolic blood pressure (SBP) of ≥ 140 mmHg or diastolic blood pressure (DBP) of ≥ 90 mmHg].

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

United Kingdom

England

Study participating centre

MRC Cyclotron Unit

London

United Kingdom

W12 0HS

Sponsor information

Organisation

Imperial College London (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration