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Combretastin A-4 phosphate in combination with carboplatin and paclitaxel chemotherapy in patients with advanced cancer

Submission date 31/03/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 31/03/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 13/07/2021	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-combretastatin-and-chemotherapy-for-people-with-advanced-solid-tumours

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2006-005417-35

Protocol serial number
2291

Study information

Scientific Title
A phase Ib/II trial of CA4P (combretastin A-4 phosphate) in combination with carboplatin and paclitaxel chemotherapy in patients with advanced cancer and advanced ovarian carcinoma

Acronym
UKCTC-207

Study objectives
1. To assess safety and tolerability of the CA4P-carboplatin-paclitaxel combination in relapsed platinum-resistant ovarian/primary peritoneal cancer
2. To gather preliminary data on the anti-tumour efficacy of the CA4P-carboplatin-paclitaxel combination in relapsed platinum-resistant ovarian/primary peritoneal cancer

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Hertfordshire Hospitals NHS Trust Local Research Ethics Committee, 21/05/2003, ref: EC2003-31

Study design
Non-randomised multicentre interventional treatment trial

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

Interventions
6 cycles (3-weekly) of:
Day 1: combretastatin A-4 phosphate 63 mg/m^2 intravenously (i.v.)
Day 2: paclitaxel 175 mg/m^2 i.v. then carboplatin AUC 5 i.v.

Follow-up every 2 months until progression or death.

Intervention Type
Other

Phase
Phase II

Primary outcome(s)
1. Computed tomography (CT) scans, measured at screening, after cycle 2, after cycle 4 and after cycle 6
2. CA-125 tumour marker, measured at screening and before every cycle

Key secondary outcome(s))

1. Duration of response
2. Progression-free survival
3. Toxicity

Clinical examination for signs of progression is assessed at every follow-up.

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. A minimum four-week interval must have passed from the time a patient last received chemotherapy, immunotherapy or radiotherapy prior to the first dose of study drugs (six weeks for therapy known to be associated with delayed toxicity such as nitrosoureas or mitomycin-C)
2. For entry into the phase II study: patients with Ovarian, Primary Peritoneal or Fallopian Tube Cancer who have relapsed following treatment with a platinum containing regime in the adjuvant or metastatic setting, with a progression-free interval (FPI) of less than 6 months.
3. Radiologically measurable disease and/or evaluable by Ca 125. To be evaluable for response by CA-125 requires 2 pre-treatment samples greater than twice the upper limit of normal.
4. Age 18 years or older
5. Eastern Cooperative Oncology Group (ECOG) performance status (PS) = 2
6. Life expectancy greater than 12 weeks
7. Adequate bone marrow function:
7.1. Absolute granulocyte count (neutrophils and bands) greater than 1500 cells/mm^3
7.2. Platelet count greater than 100,000 cells/mm^3
8. Adequate hepatic function:
8.1. Total bilirubin less than 1.5 mg/dl
8.2. Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) less than 2.5 x upper limit of normal
9. Adequate renal function: Glomerular Filtration Rate measured by EDTA
clearance greater than 50 ml/min
10. Patients must provide written and voluntary informed consent and be available for periodic follow-up
11. Fertile patients must abstain from sexual intercourse or use effective birth control
12. All women of childbearing potential (WOCBP) must have a negative serum or urine pregnancy test documented within 72 hours prior to receiving cycle 1

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

Female

Key exclusion criteria

1. Serious intercurrent infection(s) or other nonmalignant medical illnesses that are uncontrolled or whose control may be jeopardised by the complications of this therapy
2. Grade 2 (CTC v 3.0) or greater pre-existing peripheral neuropathy (motor or sensory)
3. Active brain metastasis, including symptomatic involvement, evidence of cerebral oedema by CT or MRI, radiographic evidence of progression since definitive therapy, or continued requirement for corticosteroids
4. Major surgery within four weeks prior to receiving cycle 1
5. Symptomatic peripheral vascular disease or cerebrovascular disease
6. Prior radiation involving > 30% of the bone marrow
7. Patients who have had any clinically apparent ischaemic or vascular damage from previous radiotherapy. Patients who have had radical radiotherapy to the thorax or abdomen at any time or post-operative radical radiotherapy to the pelvis. Palliative radiotherapy treatments are acceptable. Patients with rectal primaries who have received pre-operative pelvic radiotherapy or chemoradiation are eligible if the small bowel was mobile and not stuck to the tumour.
8. Psychiatric disorders or other conditions rendering patients incapable of complying with the requirements of the protocol
9. Pregnant or breast-feeding women
10. History of angina (stable or more severe, even if controlled with medications), myocardial infarction, CHF, non-controlled atrial arrhythmias or clinically significant arrhythmias including conduction abnormality, nodal junctional arrhythmias and dysrhythmias, sinus bradycardia or tachycardia, supraventricular arrhythmias, atrial fibrillation or flutter, syncope or vasovagal episodes
11. MUGA scan revealing significant heart wall abnormality or heart muscle damage
12. Uncontrolled hypertension (defined as blood pressure consistently greater than 150/100 irrespective of medication)
13. Uncontrolled hypokalemia and/or hypomagnesemia
14. ECG with evidence of prior myocardial infarction (e.g., significant Q waves), QTc > 450 msec or other clinically significant abnormalities
15. Patients taking any drug(s) known to prolong the QTc interval, which cannot be interrupted for at least four days during each 21-day treatment cycle. Patients with conditions associated with QTc prolongation
16. Concurrent investigational therapy
17. Concurrent antineoplastic therapy (radiation therapy, cytotoxic or biologic therapy)
18. Concurrent hormonal therapy with the exception of GnRH agonists in patients with hormone refractory prostate cancer, HRT, oral contraceptives, and megestrol acetate used for anorexia /cachexia
19. Receiving anticoagulation with warfarin, heparin or low molecular weight heparin other than low dose (1 mg) warfarin for maintenance of Hickman line patency
20. No previous high-dose chemotherapy with autologous bone marrow transplant (HDC-ABMT) or similar high-dose therapies

Date of first enrolment

15/11/2005

Date of final enrolment

31/12/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Medical Oncology
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Sponsor information

Organisation
East and North Hertfordshire Hospitals NHS Trust (UK)

ROR
https://ror.org/02ryc4y44

Funder(s)

Funder type
Industry

Funder Name
OXiGENE, Inc. (USA)

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?
Plain English results				No	Yes