

Saracatinib (AZD0530) and docetaxel in metastatic castrate-refractory prostate cancer

Submission date 09/08/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/10/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/05/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-docetaxel-and-saracatinib-for-prostate-cancer-spread>

Contact information

Type(s)

Scientific

Contact name

Dr Rob Jones

Contact details

Cancer Research UK Clinical Trials Unit
The Beatson West of Scotland Cancer Centre, Level 0
(partner in CACTUS - Cancer Clinical Trials Unit Scotland)
1053 Great Western Road
Glasgow
United Kingdom
G12 0YN
+44 (0)141 301 7095
robert.jones@glasgow.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

2010-021447-41

Protocol serial number

SAPROCAN VERSION 1.2: 21APR2011. 021447-41

Study information

Scientific Title

SAracatinib (AZD0530) and docetaxel in metastatic castrate-refractory PROstate CANcer: a phase I/randomised phase II study by the NCRI Prostate Clinical Studies Group

Acronym

SAPROCAN

Study objectives

To provide preliminary evidence regarding whether the addition of saracatinib (AZD0530) to first line docetaxel plus prednisolone will increase progression free survival in patients with metastatic, castrate refractory prostate cancer.

Ethics approval required

Old ethics approval format

Ethics approval(s)

West of Scotland REC 1, 07/04/2011

Study design

Phase I followed by a phase II randomised placebo-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Prostate cancer

Interventions

All patients will receive docetaxel by intravenous (iv) infusion once every 3 weeks for a maximum of 10 cycles with prednisolone 5mg twice daily by mouth from the first day of docetaxel up to at least day 21 of the final dose.

Phase I

Patients in the phase I component of the study will commence once-daily saracatinib (AZD0530) on day 11 of the first cycle of docetaxel (dose as specified). They will continue until disease progression is confirmed.

Phase II

Patients in the phase II component of the study will be randomly assigned to receive either saracatinib (AZD0530) once daily by mouth at a dose to be defined in phase I or a matching placebo. This will be taken by mouth starting 7 days prior to the first dose of docetaxel and stopping when disease progression is confirmed.

Intervention Type

Drug

Phase

Phase I/II

Drug/device/biological/vaccine name(s)

Docetaxel, prednisolone, saracatinib (AZD0530)

Primary outcome(s)

1. Phase I: To establish a safe and tolerable dose for saracatinib (AZD0530) given in combination with docetaxel and prednisolone
2. Phase II: To establish whether the efficacy of the combination of saracatinib (AZD0530) with docetaxel and prednisolone merits further study in patients with metastatic castrate-refractory prostate cancer (mCRPC)

Key secondary outcome(s)

1. Phase I: To investigate the effects of saracatinib (AZD0530) on docetaxel pharmacokinetics
2. Phase II: To estimate the effect of saracatinib (AZD0530) on bone pain in patients with mCRPC

Completion date

30/04/2015

Eligibility

Key inclusion criteria

1. Male aged 18 or over
2. Histologically or cytologically proven adenocarcinoma of the prostate with previously documented metastases
3. Proven disease progression since last change in therapy defined by at least one of the following:
 - 3.1. Prostate-specific antigen (PSA) progression as defined by the prostate cancer working group (PCWG2) criteria. This must be based on a series of at least three readings at least 7 days apart. The third reading must be greater than or equal to 2ng/ml. In the event where an intermediate reading is lower than a previous reading, then the patient will still be eligible (ie. the 3 readings do not need to be consecutive). The first of the three readings must have been obtained after commencing the previous systemic therapy, or, in the case of androgen receptor antagonists, after discontinuing.
 - 3.2. Radiographic progression as defined by Response Evaluation Criteria In Solid Tumors (RECIST) for non-bone disease
 - 3.3. The appearance of two or more new lesions on a bone scan
4. Castrate levels of serum testosterone ($<1.7\text{nmol/l}$)
5. Eastern Cooperative Oncology Group performance status (ECOG PS) = 0 or 1
6. Haemoglobin (Hb) $\geq 10\text{g/dL}$; platelets $\geq 100 \times 10^9/\text{L}$; neutrophils $\geq 1.5 \times 10^9/\text{L}$
7. Bilirubin \leq upper limit of normal (ULN) ; alanine aminotransferase (ALT), aspartate aminotransferase (AST) $\leq 1.5 \times \text{ULN}$
8. Serum Creatinine $\leq 1.5 \times \text{ULN}$ or calculated creatinine clearance $\geq 50 \text{ ml/min}$
9. Able to swallow study drugs
10. Life expectancy > 3 months
11. Provision of written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Prior cytotoxic chemotherapy for prostate cancer (patients may have received previous or ongoing bisphosphonates, e.g. zoledronate)
2. Prior intolerance of cremaphor
3. Other prior malignancy with estimated $\geq 30\%$ chance of relapse within 2 years
4. Previously identified brain metastases or spinal cord compression unless treated with full functional recovery
5. Prior radionuclide therapy for prostate cancer
6. Prior radiotherapy to $> 30\%$ of bone marrow
7. Administration of investigational agent within 30 days of first dose of study medication
8. Androgen receptor antagonist therapy during 6 weeks prior to initiation of study medication
9. Any evidence of severe or uncontrolled systemic conditions (eg. severe hepatic impairment), or current unstable or uncompensated cardiac condition which makes it undesirable for the patient to participate in the study or which could jeopardise compliance with the protocol
10. Any evidence of pneumonitis or other interstitial lung disease (bilateral, diffuse, parenchymal lung disease) or current unstable or uncompensated respiratory condition
11. Resting electrocardiogram (ECG) with measurable QTc interval of > 480 msec at 2 or more time points within a 24 hour period
12. Patients with known immunodeficiency syndrome
13. Unable to discontinue any medication or herbal supplement that may significantly modulate CYP3A4 activity or which is significantly metabolised by CYP3A4. Such drugs must have been discontinued for an appropriate period prior to starting AZD0530.
14. Unresolved toxicity \geq Common Terminology Criteria (CTC) grade 2 (except alopecia) from previous anti-cancer therapy
15. Patients with a partner of child-bearing potential who is not using a highly effective method of contraception, who are unwilling to use condoms during the study and for 30 days after the last dose of study drug
16. Known hypersensitivity to AZD0530 (saracatinib, its excipients, or drugs in its class)
17. Known malabsorption syndrome

Date of first enrolment

30/09/2011

Date of final enrolment

30/04/2015

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Cancer Research UK Clinical Trials Unit

Glasgow

United Kingdom

G12 0YN

Sponsor information

Organisation

NHS Greater Glasgow and Clyde (UK)

ROR

<https://ror.org/05kdz4d87>

Funder(s)

Funder type

Industry

Funder Name

AstraZeneca

Alternative Name(s)

AstraZeneca PLC, Pearl Therapeutics, AZ

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		21/08/2020	19/05/2022	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes