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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
09/08/2011		Protocol		
Registration date	Overall study status	Statistical analysis plan		
17/10/2011	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
19/05/2022	Cancer			

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

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Contact details

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Additional identifiers

EudraCT/CTIS number

2010-021447-41

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SAPROCAN VERSION 1.2: 21APR2011. 021447-41

Study information

Scientific Title

SAracatinib (AZD0530) and docetaxel in metastatic castrate-refactory 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

- 1. Phase I: To establish a safe and tolerable dose for saracatinib (AZD0530) given in combination with 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-refactory prostate cancer (mCRPC)

Secondary outcome measures

- 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

Overall study start date

30/09/2011

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 (<1.7nmol/l)
- 5. Eastern Cooperative Oncology Group performance status (ECOG PS) = 0 or 1
- 6. Haemoglobin (Hb) \Rightarrow 10g/dL; platelets \Rightarrow 100 x 109/L; neutrophils \Rightarrow 1.5 x109/L
- 7. Bilirubin \leq upper limit of normal (ULN); alanine aminotransferase (ALT), aspartate aminotransferase (AST) \leq 1.5 x ULN
- 8. Serum Creatinine <=1.5 x ULN or calculated creatinine clearance >= 50 ml/min
- 9. Able to swallow study drugs
- 10. Life expectancy > 3 months
- 11. Provision of written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Phase I = 3 -18, Phase II = 140

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 >= 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 ≥ 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

Scotland

United Kingdom

Study participating centre Cancer Research UK Clinical Trials Unit

Glagow United Kingdom G12 0YN

Sponsor information

Organisation

NHS Greater Glasgow and Clyde (UK)

Sponsor details

Research and Development Central Office The Tennent Institute, 1st Floor Western Infirmary General 38 Church Street Glasgow Scotland United Kingdom G11 6NT

Sponsor type

Hospital/treatment centre

Website

http://www.nhsggc.org.uk/

ROR

https://ror.org/05kdz4d87

Funder(s)

Funder type

Industry

Funder Name

AstraZeneca

Alternative Name(s)

AstraZeneca PLC, Pearl Therapeutics

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

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

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		21/08/2020	19/05/2022	No	No