ISRCTN22566729 https://doi.org/10.1186/ISRCTN22566729

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

Submission date	Recruitment status	[_] Prospectively registered
09/08/2011	No longer recruiting	[_] 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
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

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) >= 10g/dL; platelets >= 100 x 109/L; neutrophils >= 1.5 x109/L
7. Bilirubin <= upper limit of normal (ULN) ; alanine aminotransferase (ALT), aspartate aminotransferase (AST) <= 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