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SarCaBon: a randomised phase II trial of saracatinib versus placebo for cancer-induced bone pain

Submission date	Recruitment status	[X] Prospectively registered
30/01/2014	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
30/01/2014	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
28/05/2020	Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-trial-looking-at-saracatinib-for-pain-caused-by-cancer-spread-to-the-bone-sarcabon

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2013-002505-62

IRAS number

ClinicalTrials.gov number

NCT02085603

Secondary identifying numbers
15852

Study information

Scientific Title
SarCaBon: a randomised phase II trial of saracatinib versus placebo for cancer-induced bone pain

Acronym
SarCaBon

Study objectives
The aim of this randomised double-blind phase II trial is to determine whether Saracatinib has clinical efficacy as an analgesic for bone pain that is due to bone metastases in cancer patients by comparing patients' self-reported pain ratings after 4 weeks on treatment, with pain scores from patients who receive placebo

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 24/10/2013, ref: 13/YH/0263

Study design
Randomised; Interventional; Design type: Treatment

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
Topic: National Cancer Research Network; Subtopic: All Cancers/Misc Sites; Disease: All

Interventions
Saracatinib 125mg per day or placebo for 28 days

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Saracatinib

Primary outcome measure
Pain score: Whether patients self-reported pain scores are significantly lower after 4 weeks on treatment with

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2014

Completion date
31/07/2017

Eligibility

Key inclusion criteria
1. Able to give written informed consent and willing to follow the study protocol
2. Age = 16 years
3. Cytologically or histologically confirmed solid tumours of known primary site with painful bone metastases and poor control of bone pain
4. WHO performance status = 2
5. Average baseline pain score = 4 and = 9 on 10 numerical scale recorded over at least two separate days
6. Adequate baseline haematological, hepatic and renal function, defined as follows: Absolute neutrophil count = 1.5 x 109/L, Haemoglobin >9.0 g/dL (can be after transfusion), Platelet count = 100 x 109/L, Bilirubin = 1.5 x ULN, ALT or AST = 2.5 x ULN (= 5 x ULN if liver metastases), Creatinine = 1.5 x ULN
7. Ability to take and absorb oral medications
8. Female patients of childbearing potential (i.e. premenopausal females, females who have been menopausal for < 1 year and not surgically sterilized) must provide a negative pregnancy test (serum) = 7 days before study treatment begins and must agree to practice effective contraceptive measures (oral contraceptive pill, intrauterine device or diaphragm with spemicide) plus condoms during the study and for 30 days after last dose of saracatinib
9. Male patients with a partner of childbearing potential (who is not using an acceptable highly effective method of contraception) or a pregnant partner must use effective contraceptive measures (see 8) plus condoms during the study and for 3 months after the last dose of saracatinib. Patients should abstain from sperm donation during the study and for 3 months after the last dose of saracatinib

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 62; UK Sample Size: 62

Total final enrolment
13

Key exclusion criteria
1. Life expectancy less than 3 months
2. Previous or planned radiotherapy at site of pain
3. Unstable cardiac disease in last 3 months
4. History of interstitial lung disease (bilateral, diffuse parenchymal lung disease) in view of known saracatinib-related pneumonitis
5. Unable to discontinue any medication with known moderate or potent inhibitory effect on CYP3A4, or is a substrate of CYP3A4
6. Concomitant cytotoxic chemotherapy unless established on maintenance treatment for > 6 weeks (not in a clinical trial)
7. Unable to understand written or spoken English as the primary outcome is dependent on completion of the BPISF questionnaire

Date of first enrolment
01/02/2014

Date of final enrolment
01/02/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Weston Park Hospital
Sheffield
United Kingdom
S10 2SJ

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Trust (UK)

Sponsor details
Research Department
11 Broomfield Road
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

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

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			28/05/2020	No	No
HRA research summary			28/06/2023	No	No