

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

Submission date 30/01/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/01/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/05/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

Clinical Trials Information System (CTIS)

2013-002505-62

ClinicalTrials.gov (NCT)

NCT02085603

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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 = $1.5 \times 10^9/L$, Haemoglobin $>9.0 \text{ g/dL}$ (can be after transfusion),
Platelet count = $100 \times 10^9/L$, Bilirubin = $1.5 \times \text{ULN}$, ALT or AST = $2.5 \times \text{ULN}$ (= $5 \times \text{ULN}$ if liver metastases), Creatinine = $1.5 \times \text{ULN}$
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 spermicide) 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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Weston Park Hospital

Sheffield

United Kingdom

S10 2SJ

Sponsor information

Organisation

Sheffield Teaching Hospitals NHS Trust (UK)

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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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?
Basic results			28/05/2020	No	No
HRA research summary			28/06/2023	No	No