

Radium-223: evaluation of activity and surrogate response

Submission date 21/01/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/06/2026	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-of-a-new-way-to-see-how-well-radium-223-is-working-reasure>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

2013-004055-20

Protocol serial number

17391

Study information

Scientific Title

A phase II randomised trial of biomarkers to assess (dose) response in patients with metastatic castration resistant prostate cancer treated with radium-223

Acronym

REASURE

Study objectives

The aim of this trial is to identify potential markers of response to treatment with radium-223 in patients with castration-resistant prostate cancer with bone metastases.

Ethics approval required

Old ethics approval format

Ethics approval(s)

London Surrey Borders, 23/09/2014, ref: 14/LO/1385

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Treatment

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Prostate cancer

Interventions

Patients will be randomised to receive either 50kBq/kg or 80kBq/kg of radium 223. Patients in both arms will receive radium-223 every 4 weeks for up to 6 treatments. Follow up will be from 4 weeks after the last administration of radium-223. Patients will be evaluated every four months until 1 year after last administration.

Intervention Type

Other

Primary outcome(s)

The proportion of patients showing bone metastases response on diffusion weighted MRI (DW-MRI). From pre-treatment to any point after 1st injection and the end of cycle 6 will be used to define response.

Key secondary outcome(s)

N/A

Completion date

01/12/2018

Eligibility

Key inclusion criteria

1. Histologically or cytologically confirmed adenocarcinoma of the prostate.
2. Known castration resistant disease defined as:
 - 2.1. Castrate serum testosterone level: = 50 ng/dL (2.0nM)
 - 2.2. Bilateral orchidectomy or on maintenance androgen ablation therapy with LHRH agonist or polyestradiol phosphate throughout the study
 - 2.3. Serum PSA progression defined by PCWG II criteria (i.e. two consecutive increases in PSA over a previous reference value, each measurement taken at least 1 week apart)
3. Serum PSA value = 2 ng/mL
4. Available ALP result from a blood sample taken within previous 8 weeks
5. Multiple skeletal metastases (= 2 hot spots) on bone scintigraphy within previous 12 weeks
6. Age =16 years
7. ECOG performance status 0-2.
8. Life expectancy = 6 months.
9. No prior chemotherapy for CRPC (adjuvant chemotherapy for hormone naïve disease is permissible).
10. Adequate laboratory requirements:
 - 10.1. Absolute neutrophil count (ANC) greater than or equal to $1.5 \times 10^9/L$
 - 10.2. Platelet count greater than or equal to $100 \times 10^9/L$
 - 10.3. Haemoglobin greater than or equal to 10.0 g/dL (100 g/L; 6.2 mmol/L)
 - 10.4. Total bilirubin level less than or equal to 1.5 institutional upper limit of normal (ULN)
 - 10.5. ASAT and ALAT less than or equal to 2.5 x ULN
 - 10.6. Creatinine less than or equal to 1.5 x ULN
 - 10.7. Albumin greater than 30 g/L
11. Willing and able to comply with the protocol, including all assessments, scans, procedures, followup visits and examinations
12. Must be fully informed about the study and has signed the informed consent form

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Total final enrolment

36

Key exclusion criteria

1. Any prior radioisotope therapy
2. Surgery, radiation, chemotherapy, or other anticancer therapy within four weeks prior to randomisation into the study with the exception of LHRH agonists
3. Intention to commence cytotoxic chemotherapy within six months
4. Prior other malignancy within three years. Adequately treated basal cell or squamous cell skin or superficial (pTis, pTa, and pT1) bladder cancer are allowed
5. Treatment with any investigational drug within 30 days prior to randomisation into the study

6. History of visceral metastasis, or visceral metastases, as assessed by chest/abdominal/pelvic CT within previous 8 weeks
7. Malignant lymphadenopathy exceeding 1.5 cm in short-axis diameter
8. Known brain or leptomeningeal involvement
9. Imminent/established spinal cord compression based on clinical findings/MRI (can be re-screened following appropriate treatment)
10. Blood transfusion or erythropoietin stimulating agents within the four weeks prior to randomisation
11. Faecal incontinence
12. Unsuitable for MRI (patient refusal or clinical contra-indication)
13. Inadequate organ or bone marrow function
14. Any other serious illness or medical condition

Date of first enrolment

30/01/2015

Date of final enrolment

30/06/2017

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

The Institute for Cancer Research

15 Cotswold Road

Sutton

England

SM2 5NG

Sponsor information

Organisation

Royal Marsden NHS Foundation Trust

ROR

<https://ror.org/0008wzh48>

Organisation

The Institute for Cancer Research

Funder(s)

Funder type

Industry

Funder Name

Bayer Pharmaceuticals Plc (UK)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from reasure-icrctsu@icr.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Fracture risk	01/04/2021	07/05/2021	Yes	No
Results article	Disease response in bone	03/10/2023	04/10/2023	Yes	No
Results article		20/06/2026	22/06/2026	Yes	No
HRA research summary			28/06/2023	No	No