ISRCTN17805587 https://doi.org/10.1186/ISRCTN17805587

Radium-223: evaluation of activity and surrogate response

Submission date	Recruitment status	[X] Prospectively registered
21/01/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/01/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/10/2023	Cancer	

Plain English summary of protocol
http://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

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Additional identifiers

EudraCT/CTIS number
2013-004055-20

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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 contact details to request a patient information sheet

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

Phase

Phase II

Primary outcome measure
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.

Secondary outcome measures
N/A

Overall study start date
30/01/2015

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 x 109/L
10.2. Platelet count greater than or equal to 100 x109/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

Age group
Adult

Sex
Male

Target number of participants
Planned Sample Size: 38; UK Sample Size: 38

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
England

United Kingdom

Study participating centre
The Institute for Cancer Research
15 Cotswold Road

Sutton
United Kingdom
SM2 5NG

Sponsor information

Organisation
Royal Marsden NHS Foundation Trust

Sponsor details
Fulham Road
London
England
United Kingdom
SW3 6JJ

Sponsor type
Hospital/treatment centre

Website
http://www.royalmarsden.nhs.uk/pages/home.aspx

ROR
https://ror.org/0008wzh48

Organisation
The Institute for Cancer Research

Sponsor details
15 Cotswold Road
Sutton
United Kingdom
SM2 5NG

Sponsor type
Research organisation

Funder(s)

Funder type
Industry

Funder Name
Bayer Pharmaceuticals Plc (UK)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
01/12/2019

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
HRA research summary			28/06/2023	No	No
Results article	Disease response in bone	03/10/2023	04/10/2023	Yes	No