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A prospective randomised phase III study of observation versus screening MRI and preemptive treatment in castrate resistant prostate cancer patients with spinal metastasis

Submission date
28/11/2012

Recruitment status
No longer recruiting

Registration date
29/11/2012

Overall study status
Completed

Last Edited
24/03/2026

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-trial-looking-mri-scans-pick-up-early-signs-prostate-cancer-pressing-spine-prompts

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
13129

Study information

Scientific Title
A prospective randomised phase III study of observation versus screening MRI and preemptive treatment in castrate resistant prostate cancer patients with spinal metastasis

Acronym
PROMPTS

Study objectives
Does detection of radiological spinal cord compression (rSCC) by screening magnetic resonance imaging (MRI) of the spine and pre-emptive treatment reduce the incidence of clinical spinal cord compression (SCC) in asymptomatic castrate resistant prostate cancer (CRPC) patients with spinal metastasis?

More details can be found at: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=13129

Ethics approval required
Old ethics approval format

Ethics approval(s)
12/LO/1109

Study design
Randomised; Interventional; Design type: Screening

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Prostate Cancer

Interventions
Control Group: Patients followed up as per standard practice i.e. in accordance with National Institute of Clinical Excellence (NICE) guidelines, MRI spine performed if patient develops clinical neurological deficit or significant spinal pain with treatment given if there is overt SCC on MRI.

Intervention Group, Baseline screening MRI and pre-emptive treatment to sites of radiological (r) SCC; following pre-emptive treatment patients will receive an MRI scan every 6 months (rSCC is defined as radiological spinal cord compromise).

Intervention Type
Other

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/05/2015

Eligibility

Key inclusion criteria
1. Histologically / cytologically confirmed adenocarcinoma of the prostate or clinical diagnosis of prostate cancer with osteoblastic bone metastases and Prostate-specific antigen (PSA) ≥ 100ng /ml
2. Castrate resistant disease*
3. One or more spinal metastasis on imaging (technetium bone scan with confirmatory X-ay as appropriate clinically) undertaken at any time during the patients illness
4. Life expectancy of 6 months or more
5. Eastern Cooperative Oncology Group (ECOG) performance status 02
6. Written, informed consent
*(rising PSA (> 5 ng /ml and >50% rise from nadir) after luteinizing hormone releasing hormone agonist (LHRHa) therapy or orchidectomy with or without antiandrogen)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Total final enrolment
0

Key exclusion criteria
1. Back pain related to metastatic cancer, requiring regular (daily) analgesics
2. Previous active malignancy within the last 5 years other than basal cell carcinoma or low grade superficial bladder cancer
3. Current or previous spinal cord compression (SCC) or neurologic deficit
4. Brain metastasis
5. Spinal MRI within last 12 months
6. CT or PET CT scan of thorax AND abdomen within the last 6 months
7. Previous external beam radiotherapy to the vertebra or spinal surgery with the primary aim to prevent or treat SCC+
8. Serious or uncontrolled coexistent non-malignant diseases
9. Any contra indications for MRI
10. Inability to comply with neurologic and Quality of Life (QoL) assessments
11. Previous palliative radiotherapy to painful spinal metastases in now asymptomatic patients is permissible

Date of first enrolment

30/12/2012

Date of final enrolment
01/05/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
15 Cotswold Road
-
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Sponsor information

Organisation
Institute of Cancer Research Experimental Cancer Medicine Centre

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (UK) Grant Codes: C8262/A13749

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article			14/03/2022	Yes	No
Plain English results		24/03/2026	24/03/2026	No	Yes