

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/11/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/03/2022	Condition category Cancer	<input type="checkbox"/> 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

Phase

Phase III

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) $\geq 100\text{ng/ml}$
 2. Castrate resistant disease*
 3. One or more spinal metastasis on imaging (technetium bone scan with confirmatory X-ray 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 ($> 5\text{ ng/ml}$ 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

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

Sutton

United Kingdom

SM2 5NG

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

Not provided at time of registration

IPD sharing plan summary**Study outputs**

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