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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

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|---|---|---|
| **Submission date**<br>28/11/2012 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>29/11/2012 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[X] Results |
| **Last Edited**<br>14/03/2022 | **Condition category**<br>Cancer | [_] 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Screening

### Participant information sheet

### 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 measure
Not provided at time of registration

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
30/12/2012

### 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

### Age group
Adult

### Sex
Male

### Target number of participants
Planned Sample Size: 541; UK Sample Size: 541

### 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
England

United Kingdom

### Study participating centre
**15 Cotswold Road**
Sutton
United Kingdom
SM2 5NG

## Sponsor information

### Organisation
Institute of Cancer Research Experimental Cancer Medicine Centre

### Sponsor details
Cancer Research
123 Old Brompton Road
London
United Kingdom
SW7 3RP

**Sponsor type**
Research organisation

**Website**
http://www.ecmcnetwork.org.uk/network-centres/london-institute-cancer-research/

**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, CRUK

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Other non-profit organizations

**Location**
United Kingdom

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**
Not provided at time of registration

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

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