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 | Recruitment status No longer recruiting | [X] Prospectively registered | | |
|-------------------------------|---|--------------------------------|--|--|
| 28/11/2012 | | ☐ Protocol | | |
| Registration date 29/11/2012 | Overall study status Completed | Statistical analysis plan | | |
| | | [X] Results | | |
| Last Edited 14/03/2022 | Condition category | [] Individual participant data | | |
| 14/03/2022 | Cancer | | | |

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

Contact name

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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