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A randomised phase III trial of low dose daily dexamethasone versus intermittent dexamethasone versus prednisolone in hormone refractory prostate cancer (The PoD Trial)

Submission date	Recruitment status	[_] Prospectively registered
29/09/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/05/2018	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2005-006018-16

Protocol serial number
N0258175363

Study information

Scientific Title
A randomised phase III trial of low dose daily dexamethasone versus intermittent dexamethasone versus prednisolone in hormone refractory prostate cancer (The PoD Trial)

Acronym
PoD

Study objectives
The trial aims to evaluate and compare the efficacy of two regimens of dexamethasone (low dose daily and intermittent) and compare them with the standard hormone treatment (Prednisolone) in Hormone Refractory Prostate Cancer (HRPC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Royal Marsden NHS Regional Ethics Committee, 24/07/2008, ref : 06/Q0801/2

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

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

Interventions
Randomised test intervention vs standardized intervention, non-blinded (Phase III)

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
dexamethasone versus prednisolone

Primary outcome(s)

To evaluate the PSA response rate of daily dexamethasone and of intermittent dexamethasone in patients with hormone refractory prostate cancer.

Key secondary outcome(s)
Added 24 July 2008:
1. To evaluate the clinical and biochemical parameters which influence PSA response to oral steroids in HRPC
2. To evaluate the duration of PSA response to dexamethasone in HRPC
3. To evaluate the time to PSA progression on dexamethasone in HRPC
4. To evaluate the objective response rate using RECIST criteria of dexamethasone in HRPC
5. To evaluate the effect of dexamethasone on pain control and time to skeletal events in HRPC
6. To evaluate the effect of dexamethasone on alkaline phosphatase and haemoglobin in HRPC
7. To evaluate the effect on levels of steroid hormones and steroid metabolites
8. To evaluate the safety and tolerability of dexamethasone in HRPC
9. To evaluate the effect of dexamethasone on overall survival in HRPC

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Patients with histologically or cytologically confirmed adenocarcinoma of the prostate to sclerotic bone metastases/increased tracer uptake on bone scan in a patient presenting with a PSA>100
2. Serum testosterone <2nmol/l
3. Ongoing androgen deprivation therapy with LHRH analogues or bilateral orchidectomy
4. Progressive disease defined as a PSA rise using 3 serum PSA measurements, each obtained at least 7 days apart within the 3 months prior to start of trial
5. Patient with progression of measurable disease (RECIST) or progression of bone disease must also fit the criterion for PSA progression
6. PSA >5
7. Life expectancy of >3 months
8. Stable/optimum analgesia
9. ECOG performance status 0-3

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria

1. Previous radiotherapy to the head and neck region
2. Previous malignancy except non-melanoma skin cancer
3. Pre-existing hearing loss or significant auditory pathology
4. Previous or concurrent illness, which in the investigators opinion would interfere with either completion of therapy or follow-up
5. Concomitant chemotherapy is not permitted

Date of first enrolment
01/02/2006

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Academic Urology Unit
Surrey
United Kingdom
SM2 5PT

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
The Royal Marsden NHS Foundation Trust (UK)

Funder Name

NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

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	results	01/04/2015		Yes	No