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A randomised phase II trial of dexamethasone and aspirin (DA) versus dexamethasone, diethylstilboestrol and aspirin (DAS) in locally advanced or metastatic cancer of the prostate

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 19/10/2018	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-dexamethasone-aspirin-and-diethylstilbestrol-for-men-with-prostate-cancer-that-has-spread

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00316927

Secondary identifying numbers
N0205108850

Study information

Scientific Title
A randomised phase II trial of dexamethasone and aspirin (DA) versus dexamethasone, diethylstilboestrol and aspirin (DAS) in locally advanced or metastatic cancer of the prostate

Study objectives
1. To assess the response rate, survival and quality of life of patients with locally advanced or metastatic prostate cancer
2. To assess if deferred diethystilboestrol offers similar results with fewer side effects

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
Randomised phase II clinical trial, 130 in each arm:
Group 1: receiving 'DA' which is a combination of dexamethasone, aspirin and ranitidine
Group 2: receiving 'DAS' dexamethasone, aspirin, ranitidine and diethylstilbestrol in combination

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Dexamethasone, aspirin, ranitidine, diethylstilboestrol

Primary outcome measure
1. PSA response rate
2. Quality of life

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2001

Completion date
01/01/2005

Eligibility

Key inclusion criteria
North East Thames region (Whipps Cross, Oldchurch, King George, St. Bartholomew's).
Patients over the age of 18 years who have locally advanced metastatic prostate specific antigen (PSA)-positive adenocarcinoma after failure of gonadotropin releasing hormone (GnRH) analogue therapy, radiation therapy, surgery or any combination of these.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
260

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2001

Date of final enrolment

01/01/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Medical Oncology Department
London
United Kingdom
EC1A 7BE

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
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Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Barts and The London NHS Trust (UK)

Funder Name
Orchid Cancer Appeal (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Plain English results				No	Yes
Results article	results	15/02/2011		Yes	No