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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

Registration date
12/09/2003

Last Edited
19/10/2018

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

ClinicalTrials.gov (NCT)
NCT00316927

Protocol serial number

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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
1. PSA response rate
2. Quality of life

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Male

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
United Kingdom

England

Study participating centre

Medical Oncology Department
London
United Kingdom
EC1A 7BE

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Barts and The London NHS Trust (UK)

Funder Name
Orchid Cancer Appeal (UK)

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	15/02/2011		Yes	No
Plain English results				No	Yes