

# 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

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/10/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> 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

### Contact name

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### Contact details

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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 diethylstilboestrol 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?
<a href="#">Results article</a>	results	15/02/2011		Yes	No
<a href="#">Plain English results</a>				No	Yes