

# 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

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 diethylstilboestrol 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

United Kingdom

SW1A 2NL

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