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

#### Contact name

Dr Jonathan Shamash

## Contact details

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# Additional identifiers

ClinicalTrials.gov (NCT)

NCT00316927

Protocol serial number

# 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

# 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