# A randomised phase III trial of docetaxel plus prednisolone vs docetaxel with prednisolone plus either zoledronic acid, strontium-89 or both agents combined

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
24/08/2005		☐ Protocol		
<b>Registration date</b> 08/09/2005	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
24/03/2022	Cancer			

#### Plain English summary of protocol

http://www.cancerhelp.org.uk/trials/a-trial-looking-at-docetaxel-zoledronic-acid-and-strontium-89-for-prostate-cancer-that-has-spread-to-the-bones

## Study website

http://www.trapeze.bham.ac.uk

# Contact information

# Type(s)

Scientific

#### Contact name

**Prof Nicholas James** 

#### Contact details

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# Additional identifiers

# **EudraCT/CTIS** number

2004-002295-41

#### **IRAS** number

#### ClinicalTrials.gov number

NCT00554918

#### Secondary identifying numbers

HTA 06/303/205; PR2100

# Study information

#### Scientific Title

A randomised phase III trial of docetaxel plus prednisolone vs docetaxel with prednisolone plus either zoledronic acid, strontium-89 or both agents combined (TRAPEZE)

#### Acronym

**TRAPEZE** 

#### Study objectives

Study aim: To compare the efficacy and safety of the four clinical trial arms in the treatment of hormone refractory prostate cancer (HRPC0 patients).

#### Ethics approval required

Old ethics approval format

## Ethics approval(s)

South West Research Ethics Committee, 09/11/2004, ref: 04/MRE06/48

# Study design

Phase III randomised controlled trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Patient information sheet can be found at http://www.trapeze.bham.ac.uk/documents /TRAPEZE\_PatientInfo-v2.pdf

#### Health condition(s) or problem(s) studied

Prostate cancer

#### **Interventions**

Current interventions as of 15/01/2009:

- 1. Docetaxel (Taxotere®) 75 mg/m2 as a one hour intravenous infusion every 3 weeks for a maximum of 6 cycles.
- 2. Docetaxel (Taxotere®) as a one hour intravenous infusion every 3 weeks for a maximum of 6 cycles with Zoledronic acid (Zometa®) every 3 weeks. Zoledronic acid will then continue alone every 4 weeks until you or your doctor wishes to discontinue it.
- 3. Docetaxel (Taxotere®) as a one hour intravenous infusion every 3 weeks for a maximum of 6 cycles and one treatment of Strontium-89 given 28 days after the last dose of Docetaxel (Taxotere) as a short intravenous injection.
- 4. Docetaxel (Taxotere®) as a one hour intravenous infusion every 3 weeks for a maximum of 6 cycles, followed by one treatment of Strontium-89 given 28 days later. Zoledronic acid (Zometa®) will be given every 3 weeks throughout the treatment. Zoledronic acid will then continue alone every 4 weeks until you or your doctor wishes to discontinue it.

As part of the main treatment the participants will also be given steroid tablets (prednisolone) to take during the course of treatment with docetaxel. In addition they will receive extra steroid tablets (dexamethasone) for a few days around each infusion of chemotherapy to decrease the potential side effects of docetaxel (allergic reactions and fluid retention).

#### Previous interventions:

A randomised phase II feasibility study of Docetaxel (Taxotere) plus Prednisolone versus Docetaxel (Taxotere) plus Prednisolone plus Zoledronic acid (Zometa) versus Docetaxel (Taxotere) plus Prednisolone plus Strontium-89 versus Docetaxel (Taxotere) plus Prednisolone plus Zoledronic acid (Zometa) plus Strontium-89 in Hormone Refractory Prostate Cancer metastatic to bone

#### Intervention Type

Drug

#### Phase

Phase III

#### Drug/device/biological/vaccine name(s)

Docetaxel (Taxotere®), prednisolone, zoledronic acid (Zometa®), strontium-89

#### Primary outcome measure

Current primary outcome measures as of 15/01/2009:

The following will be assessed every month for the first three months and then every three months until death:

- 1. Toxicity and tolerability of docetaxel + synchronous zoledronic acid (Zometa®)
- 2. Toxicity and tolerability of docetaxel + sr-89
- 3. Toxicity and tolerability of docetaxel + synchronous zoledronic acid (Zometa®) + Sr-89

#### Previous primary outcome measures:

- 1. Toxicity and Tolerablity of Docetaxel + Synchronous Zoledronic acid (Zometa)
- 2. Toxicity and tolerablity of Docetaxel + Sr-89
- 3. Toxicity and tolerablity of Docetaxel + synchronous Zoledronic acid (Zometa) + Sr-89

#### Secondary outcome measures

- 1. Health care economic analysis
- 2. Changes in bone mineral density
- 3. Biological profiling for prognostic and predictive indicators

#### Overall study start date

01/04/2007

#### Completion date

01/03/2016

# **Eligibility**

#### Key inclusion criteria

- 1. Age > 18 years
- 2. Histologically/cytologically proven prostate cancer or multiple sclerotic bone metastases with prostate specific antigen (PSA) >100 ng/ml without histological confirmation
- 3. Radiological evidence of bone metastatsis
- 4. Prior hormonal therapy for prostate cancer, resulting in serum testosterone <50 ng/dl: bilateral orchidectomy, and/or medical castration by LHRH agonist therapy
- 5. Documented disease progression, defined by one of the following: elevated PSA (progressive rise) and/or progression of any unidemensionally or bidimensionally measurable malignant lesion at least one new lesion identified on bone scan
- 7. Life expectancy > 3 months
- 8. Eastern Cooperative Oncology Group (ECOG) performance status 0-2
- 9. Adequate haematological function
- 10. Adequate renal and hepatic function
- 11. Written Informed Consent

#### Participant type(s)

Patient

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Male

## Target number of participants

618 split into 4 groups

#### Key exclusion criteria

- 1. Prior cytotoxic chemotherapy for HRPC, other than estramustine monotherapy
- 2. Prior radiotherapy to more than 25% of the bone marrow or whole pelvic irradiation
- 3. Prior radionuclide therapy for HRPC
- 4. Prior tretament with a bisphosphonate for any reason within previous 2 months
- 5. Malignant disease within the previous 5 years, other than adequatly treated basal cell

#### carcinoma

- 6. Known brain or leptomeningeal metastases
- 7. Symptomatic peripheral neuropathy > grade 2 (NCI CTC)
- 8. Known hypersensitivity to bisphosphonates
- 9. Concurrent enrolment in any other investigational clinical trial
- 10. Treatment with any other investigational compound within previous 30 days
- 11. Any condition, which, in the opion of the investigator, might interfere with the safety or evaluation of the study objectives

# Date of first enrolment

01/04/2007

#### Date of final enrolment

19/07/2013

# Locations

#### Countries of recruitment

England

Scotland

United Kingdom

Wales

# Study participating centre The Queen Elizabeth Hospital

Edgbaston Birmingham United Kingdom B15 2TH

## Study participating centre Edinburgh Cancer Centre

Western General Hospital Crewe Road Edinburgh United Kingdom EH4 2XU

# Study participating centre Christie Hospital NHS Trust

Wilmslow Road Manchester United Kingdom M20 4BX

# Study participating centre The Royal Marsden Hospital

Downs Road Sutton United Kingdom SM2 5PT

# Study participating centre The Royal Marsden Hospital

Fulham Road Chelsea London United Kingdom SW3 6JJ

# Study participating centre Beatson West of Scotland Cancer Centre

1053 Great Western Road Glasgow United Kingdom G12 0YN

# Study participating centre Aberdeen Royal Infirmary

Foresterhill Aberdeen United Kingdom AB25 2ZN

# Study participating centre Wishaw General Hospital

50 Netherton Street Wishaw United Kingdom ML2 0DP

# Study participating centre Cheltenham General Hospital

Sandford Road Cheltenham United Kingdom GL53 7AN

# Study participating centre Gloucester Royal Hospital

Great Western Road Gloucester United Kingdom GL1 3NN

# Study participating centre University Hospital Ayr

Dalmellington Road Ayr United Kingdom KA6 6DX

# Study participating centre Ipswich Hospital

Heath Road Ipswich United Kingdom IP4 5PD

# Study participating centre Queen Alexandra Hospital

Cosham Portsmouth United Kingdom PO6 3LY

# Study participating centre Velindre Hospital Velindre Road

Whitchurch

Cardiff United Kingdom CF14 2TL

# Study participating centre Maidstone Hospital

Hermitage Lane Maidstone United Kingdom ME16 9QQ

# Study participating centre St James' University Hospital

Beckett Street Leeds United Kingdom LS9 7TF

# Study participating centre Royal Albert Edward Infirmary

Wigan Lane Wigan United Kingdom WN1 2NN

# Study participating centre Southampton University Hospital

Tremona Road Southampton United Kingdom SO16 6YD

# Study participating centre Weston General Hospital

Grange Road Weston-super-Mare United Kingdom BS23 4TQ

# Study participating centre Dorset County Hospital

Williams Avenue Dorchester United Kingdom DT1 2JY

# Study participating centre Forth Valley Royal Hospital

Stirling Road Larbert United Kingdom FK5 4WR

## Study participating centre Royal Bournemouth Hospital

Castle Lane East Bournemouth United Kingdom BH7 7DW

# Study participating centre Poole Hospital

Longfleet Road Poole United Kingdom BH15 2JB

# Study participating centre Royal Free Hospital

Pond Street London United Kingdom NW3 2QG

# Study participating centre Huddersfield Royal Infirmary

Lindley Huddersfield United Kingdom HD3 3EA

# Study participating centre Bradford Royal Infirmary

Duckworth Lane Bradford United Kingdom BD9 6RJ

# Study participating centre Royal Derby Hospital

Uttoxeter Road Derby United Kingdom DE22 3NE

# Study participating centre Royal Preston Hospital

Sharoe Green Lane Fulwood Preston United Kingdom PR2 9HT

# Study participating centre Calderdale Royal Hospital

Salterhebble Halifax United Kingdom HX3 0PW

# Sponsor information

# Organisation

University of Birmingham (UK)

# Sponsor details

Edgbaston Birmingham England United Kingdom B15 2TT

#### Sponsor type

University/education

#### Website

http://www.bham.ac.uk

#### **ROR**

https://ror.org/03angcq70

# Funder(s)

#### Funder type

Government

#### **Funder Name**

Health Technology Assessment Programme

#### Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

#### **Funding Body Type**

Government organisation

## **Funding Body Subtype**

National government

#### Location

United Kingdom

# **Results and Publications**

## Publication and dissemination plan

The primary outcome results and health economic results of the trial were submitted for publication in peer-reviewed journals, and the full trial results submitted for peer review and publication to the NIHR (UK). Published results were disseminated to investigators at participating sites, who will further disseminate the results to trial participants on request.

Secondary publications and presentations must be reviewed and authorised by the Trial's Steering Committee. Please contact the TRAPEZE trial office for further information at TRAPEZE@trials.bham.ac.uk.

# Intention to publish date

01/06/2016

# Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository. Repository: European Medicines Agency (EMA)'s European Clinical Trials Database, EudraCT V10.

URL: https://eudract.ema.europa.eu/

# IPD sharing plan summary

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2016		Yes	No
Results article	results	01/07/2016		Yes	No
Results article	results	01/04/2017		Yes	No
Plain English results			24/03/2022	No	Yes