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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
24/08/2005

Recruitment status
No longer recruiting

Registration date
08/09/2005

Overall study status
Completed

Last Edited
24/03/2022

Condition category
Cancer

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

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

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2004-002295-41

ClinicalTrials.gov (NCT)
NCT00554918

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
1. Health care economic analysis
2. Changes in bone mineral density
3. Biological profiling for prognostic and predictive indicators

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

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
United Kingdom

England

Scotland

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
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United Kingdom
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Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Royal Preston Hospital
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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)

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			24/03/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes