ISRCTN15704862 https://doi.org/10.1186/ISRCTN15704862

Testing radical prostatectomy in men with oligometastatic prostate cancer that has spread to the bone

Submission date 20/01/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 05/02/2016	**Overall study status** Completed	
Last Edited 11/01/2023	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-surgery-for-men-with-prostate-cancer-that-has-spread-to

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Testing Radical prostatectomy in men with prostate cancer and oligoMetastases to the bone (TRoMbone): a randomised controlled feasibility trial

Acronym
TRoMbone

Study objectives
It is feasible to randomise men with oligometastatic prostate cancer between treatment-as-usual and treatment-as-usual plus radical prostatectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford Research Ethics Committee, 14/09/2016, ref: 16/SC/0376

Study design
Interventional multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Newly diagnosed oligometastatic prostate cancer (1-3 skeletal lesions; no visceral lesions)

Interventions
Current interventions as of 11/05/2017:
1. Radical prostatectomy (including extended pelvic lymphadenectomy) plus standard care
2. Standard care
The total duration of follow-up is 3 months in both arms and then they revert to standard NHS follow-up care

Previous interventions:
1. Radical prostatectomy (including extended pelvic lymphadenectomy) plus treatment-as-usual (androgen deprivation therapy)
2. Treatment-as-usual (androgen deprivation therapy)
The total duration of follow-up is 6 months in both arms and then they revert to standard NHS follow-up care.

Intervention Type
Procedure/Surgery

Primary outcome measure
Current secondary outcome measures as of 18/10/2017:
Feasibility to randomise, measured at 3 months

Previous primary outcome measures:
Feasibility to randomise, measured at 6 months

Secondary outcome measures
Current primary outcome measures as of 18/10/2017:
1. Quality of life, measured by the EQ5D5L questionnaire at baseline and 3 months
2. Time to castrate resistance, assessed by PSA measurements at 3 months and then ongoing as routine NHS follow-up care schedules

Previous secondary outcome measures:
1. Quality of life, measured by the EQ5D5L questionnaire at baseline, 6 weeks, 3 months and 6 months
2. Time to castrate resistance, assessed by PSA measurements at 6 weeks, 3 months, 6 months, and then ongoing as routine NHS follow-up care schedules

Overall study start date
20/02/2017

Completion date
03/08/2018

Eligibility

Key inclusion criteria
Men under 75 years old with locally resectable, oligometastatic prostate cancer, and fit for radical prostatectomy

Participant type(s)
Patient

Age group
Mixed

Sex
Male

Target number of participants
50

Key exclusion criteria
Current exclusion criteria as of 18/10/2017:
1. Contraindications to radical prostatectomy
2. Visceral metastases
3. Prior radiotherapy to the abdomen/pelvis or to skeletal metastases
4. Any systemic therapy of prostate cancer (including standard care) for 12 or more months
5. Participation in another prostate cancer clinical trial

Previous exclusion criteria:
1. Contraindications to radical prostatectomy
2. Visceral metastases
3. Prior radiotherapy to the abdomen/pelvis or to skeletal metastases
4. Any systemic therapy of prostate cancer (including treatment-as-usual) for 3 or more months
5. Participation in another prostate cancer clinical trial

Date of first enrolment
19/05/2017

Date of final enrolment
18/04/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University Hospitals
United Kingdom
OX3 7LE

Study participating centre
University College London Hospitals
United Kingdom
W1G 8PH

Study participating centre
Royal Surrey County Hospital
United Kingdom
GU2 7XX

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Oxford
Oxford
England
United Kingdom
OX3 7DQ

Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Prostate Cancer Foundation

Alternative Name(s)
CaP CURE, PCF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Publication and dissemination plan

To be confirmed at a later date

Intention to publish date
20/11/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a repository and not made available as they will form the basis for a further large randomized controlled trial.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V3.0	30/10/2017	30/11/2017	No	No
HRA research summary			28/06/2023	No	No