

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 05/02/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/01/2023	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English Summary

<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

Contact name

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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 hypothesis

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

Condition

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

Overall study end date

03/08/2018

Eligibility

Participant 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

Participant 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

Recruitment start date

19/05/2017

Recruitment end date

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