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The PACE Study

Submission date 25/02/2015	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 25/02/2015	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 28/02/2023	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-surgery-conventional-radiotherapy-and-stereotactic-radiotherapy-for-localised-prostate-cancer-pace

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01584258

Secondary identifying numbers
12628

Study information

Scientific Title
International randomised study of laparoscopic prostatectomy vs stereotactic body radiotherapy (SBRT) and conventionally fractionated radiotherapy vs SBRT for early stage organ-confined prostate cancer

Study objectives
The aim of this study is to assess whether hypofractionated stereotactic body radiotherapy (SBRT) offers therapeutic benefit over prostatectomy or conventionally fractionated radiotherapy for people with early stage organ-confined prostate cancer. Profound hypofractionation with SBRT has the potential to achieve equivalent tumour control rates compared to surgery and conventional radiotherapy while reducing radiation to normal tissues (bladder, rectal and penile bulb) and minimising radiation-induced side effects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Chelsea NRES, 25/01/12, ref: 11/LO/1915

Study design
Randomised; Interventional; Design type: Treatment

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 contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
Current intervention as of 17/02/2020:
1. Radiotherapy: Conventionally fractionated radiotherapy: delivered to a dose of 60 Gy in 20 fractions (PACE-C) or 62 Gy in 20 fractions (PACE-B)
2. SBRT - hypofractionated stereotactic body radiotherapy: delivered to a dose of 36.25 Gy in 5 fractions
3. Surgery: prostatectomy surgery

In PACE-A low- and intermediate-risk patients will be randomised between surgery (control) and SBRT.
In PACE-B low- and intermediate-risk patients will be randomised between radiotherapy (control) and SBRT.
In PACE-C intermediate- and high-risk patients will be randomised between radiotherapy (control) and SBRT.

Previous intervention:
1. Radiotherapy: Conventionally fractionated radiotherapy: delivered to a dose of 78 Gy in 2 Gy fractions
2. SBRT - hypofractionated stereotactic body radiotherapy: delivered to a dose of 36.25 Gy in 5 fractions
3. Surgery: laparoscopic prostatectomy

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measures as of 17/02/2020:
For PACE-A (surgery vs SBRT cohort):
1. Urinary incontinence (number of absorbent pads required per day to control leakage) measured by the Expanded Prostate Cancer Index (EPIC) questionnaire at 2 years post-treatment
2. Bowel bother summary score from the EPIC questionnaire at 2 years post-treatment

For PACE-B and PACE-C (conventionally fractionated radiotherapy vs SBRT cohorts):
Freedom from biochemical (Phoenix definition) or clinical (commencement [PACEB] or re commencement [PACEC] of androgen deprivation therapy, local recurrence, nodal recurrence and distant metastases) failure at 5 years post-randomisation

Previous primary outcome measures:
Biochemical progression-free survival: Phoenix definition for conventional radiotherapy and SBRT arms, >0.2 ng/ml for surgical arm. The main time point of interest is 5 years post treatment.

Secondary outcome measures
Current secondary outcome measures as of 17/02/2020:
For PACE-A:
Freedom from biochemical (Phoenix definition for SBRT arm, >0.2 ng/ml for surgical arm) or clinical (commencement of androgen deprivation therapy, local recurrence, nodal recurrence and distant metastases) failure at 5 years post-treatment

For all cohorts:
1. Toxicity assessment for surgical and SBRT arm: CTCAE and RTOG for acute and late toxicity. Clavien scale used to assess acute post-surgical complications for surgical patients only.
2. Toxicity assessment for conventionally fractionated and SBRT arm: CTCAE and RTOG acute and late toxicity scoring
3. Patient reported outcomes and quality of life assessment for all treatment arms: erectile function (IIEF-5), IPSS, Vaizey score, EPIC-26 and PR-25
4. Disease-specific and overall survival
5. Progression-free survival: radiographic, clinical or biochemical evidence of local or distant

failure
6. Commencement (PACE-A and PACE-B)/recommencement (PACE-C) of androgen deprivation therapy (LHRH analogues, anti-androgens, orchidectomy)

Previous secondary outcome measures:
1. Toxicity assessment for surgical and SBRT arm: CTCAE and RTOG for acute and late toxicity. Clavien scale used to assess acute post-surgical complications for surgical patients only.
2. Toxicity assessment for conventionally fractionated and SBRT arm: CTCAE and RTOG acute and late toxicity scoring
3. Patient reported outcomes and quality of life assessment for all treatment arms: Erectile function (IIEF-5), IPSS, Vaizey score, EPIC-26 and PR-25.
4. Disease-specific and overall survival
5. Progression-free survival: radiographic, clinical or biochemical evidence of local or distant failure.
6. Commencement of androgen deprivation therapy (LHRH analogues, anti-androgens, orchidectomy).

Overall study start date
01/08/2012

Completion date
01/09/2016

Eligibility

Key inclusion criteria
1. Histological confirmation of prostate adenocarcinoma with a minimum of 10 biopsy cores taken within last 18 months.
2. Gleason score = 3+4
3. Men aged at least18
4. Clinical and MRI stage T1c –T2c, N0-X, M0-X
5. PSA = 20 ng/ml
6. Pre-enrollment PSA must be completed within 60 days of registration
7. Patients belonging in one of the following risk groups according to the National Comprehensive Cancer Network (www.nccn.org):
7.1. Low risk: Clinical stage T1-T2a and Gleason = 6 and PSA < 10 ng/ml, or
7.2. Intermediate risk includes any one of the following:
7.2.1. Clinical stage T2b orT2c
7.2.2. PSA 10-20 ng/ml
7.2.3. Gleason 7
8. WHO performance status 0 - 2
9. Prostate volume = 90 cc measured within 6 months of randomisation
10. Ability of the research subject to understand and the willingness to sign a written informed consent document

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
Planned Sample Size: 1716; UK Sample Size: 200

Key exclusion criteria
1. Clinical stage T3 or greater
2. Gleason score = 4 + 3
3. High risk disease defined by National Comprehensive Cancer Network (www.nccn.org)
4. < 10 prostate biopsies taken
5. Previous malignancy within last 5 years except basal cell carcinoma or squamous cell carcinoma of the skin
6. Prior pelvic radiotherapy
7. Prior androgen deprivation therapy (including androgen agonists and antagonists)
8. Any prior active treatment for prostate cancer. Patients previously on active surveillance are eligible if they continue to meet all other eligibility criteria.
9. Prior transurethral resection of the prostate (TURP) for benign prostatic hypertrophy
10. Life expectancy <5 years
11. Bilateral hip prostheses or any other implants/hardware that would introduce substantial CT artifacts
12. Medical conditions likely to make radiotherapy inadvisable eg inflammatory bowel disease, significant urinary symptoms
13. Anticoagulation with warfarin/bleeding tendency making fiducial placement or surgery unsafe in the opinion of the clinician.
14. Medical condition/ implant that prohibits MRI
15. Participation in another concurrent treatment protocol

Date of first enrolment
01/08/2012

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Canada

England

Ireland

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
The Royal Marsden NHS Foundation Trust
Fulham Road
London
United Kingdom
SW3 6JJ

Study participating centre
East and North Hertfordshire NHS Trust
Mount Vernon Cancer Centre,
The Clock Tower,
Rickmansworth Road,
Northwood
Middlesex
United Kingdom
HA6 2RN

Study participating centre
Royal Marsden Hospital, Sutton
Downs Rd
Sutton
United Kingdom
SM2 5PT

Study participating centre
Kingston Hospital
Galsworthy Rd
Kingston upon Thames
United Kingdom
KT2 7QB

Study participating centre
Churchill Hospital
Old Road
Headington
Oxford
United Kingdom
OX3 7LE

Study participating centre
James Cook University Hospital
Marton Rd
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Freeman Hospital
Freeman Rd
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Belfast City Hospital
51 Lisburn Rd
Belfast
United Kingdom
BT9 7AB

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
University Hospital Coventry and Warwickshire
Clifford Bridge Rd
Coventry
United Kingdom
CV2 2DX

Study participating centre

Addenbrooke's Hospital
Hills Rd
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Hinchingbrooke Hospital
Parkway
Hinchingbrooke
United Kingdom
PE29 6NT

Study participating centre
Sunderland Royal Hospital
Kayll Rd
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Clatterbridge Cancer Centre
Clatterbridge Rd
Birkenhead
United Kingdom
CH63 4JY

Study participating centre
West Suffolk Hospital
Hardwick Ln
Bury St Edmunds
United Kingdom
IP33 2QZ

Study participating centre
Nottingham City Hospital
Hucknall Rd
Nottingham
United Kingdom
NG5 1PB

Study participating centre
St Bartholomew's Hospital
W Smithfield
London
United Kingdom
EC1A 7BE

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Charing Cross Hospital
Fulham Palace Rd
Hammersmith
London
United Kingdom
W6 8RF

Study participating centre
Royal Free Hospital
Pond St
Hampstead
London
United Kingdom
NW3 2QG

Study participating centre
University College Hospital
235 Euston Rd
Bloomsbury
London
United Kingdom
NW1 2BU

Study participating centre

Lincoln County Hospital
Greetwell Rd
Lincoln
United Kingdom
LN2 5QY

Study participating centre
Pilgrim Hospital
Sibsey Rd
Boston
United Kingdom
PE21 9QS

Study participating centre
Norfolk & Norwich University Hospital
Colney Ln
Norwich
United Kingdom
NR4 7UY

Study participating centre
Velindre Cancer Centre
Velindre Rd
Cardiff
United Kingdom
CF14 2TL

Study participating centre
Glan Clwyd Hospital
Rhuddlan Rd
Bodelwyddan
Rhyl
United Kingdom
LL18 5UJ

Study participating centre
Weston Park Hospital
Whitham Rd
Broomhall

Sheffield
United Kingdom
S10 2SJ

Study participating centre
Beatson West of Scotland Cancer Centre
1053 Great Western Rd
Glasgow
United Kingdom
G12 0YN

Study participating centre
Southend University Hospital
Prittlewell Chase
Westcliff-on-Sea
Southend-on-Sea
United Kingdom
SS0 0RY

Study participating centre
Colchester Hospital
Turner Rd
Mile End
Colchester
United Kingdom
CO4 5JL

Study participating centre
Royal Cornwall Hospital
Treliske
Truro
United Kingdom
TR1 3LQ

Study participating centre
Derriford Hospital
Derriford Rd
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Torbay Hospital
Newton Rd
Torquay
United Kingdom
TQ2 7AA

Study participating centre
Bristol Haematology and Oncology Centre
22 Horfield Rd
Bristol
United Kingdom
BS2 8ED

Study participating centre
Christie Hospital
Wilmslow Rd
Manchester
United Kingdom
M20 4BX

Study participating centre
The Queen Elizabeth Hospital
Gayton Rd
King's Lynn
United Kingdom
PE30 4ET

Study participating centre
Western General Hospital
Crewe Rd S
Edinburgh
United Kingdom
EH4 2XU

Study participating centre
Maidstone Hospital
Hermitage Ln
Maidstone

United Kingdom
ME16 9QQ

Study participating centre
Musgrove Park Hospital
Parkfield Dr
Taunton
United Kingdom
TA1 5DA

Study participating centre
North Middlesex University Hospital
Sterling Way
London
United Kingdom
N18 1QX

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

Study participating centre
Beacon Hospital
Beacon Court
Bracken Road
Sandyford Industrial Estate
Dublin
Ireland
D18 AK68

Study participating centre
St James's Hospital
James's Street
The Liberties
Dublin
Ireland
D08 NHY1

Study participating centre
Beaumont Hospital
Beaumont Rd
Dublin
Ireland
D09 V2N0

Study participating centre
St Luke's Hospital
Oakland Drive
Highfield Road
Dublin
Ireland
D06 HH36

Study participating centre
Odette Cancer Centre
Bayview Avenue
Toronto
Canada
M4N 3M5

Study participating centre
Juravinski Cancer Centre
699 Concession Street
Hamilton
Canada
L8V 5C2

Study participating centre
Lakeridge Health
1 Hospital Court
Oshawa
Canada
L1G 2B9

Study participating centre
Northeast Cancer Centre
41 Ramsey Lake Rd

Sudbury
Canada
P3E 5J1

Study participating centre
Walker Family Cancer Centre
1200 Fourth Ave
St. Catharines
Canada
L2S 0A9

Study participating centre
Hôpital Charles-LeMoyne
3120 Taschereau Blvd
Greenfield Park
Longueuil
Canada
J4V 2H1

Study participating centre
London Health Sciences Centre
800 Commissioners Rd E
London
Canada
N6A 5W9

Study participating centre
Ottawa Hospital
501 Smyth Rd
Ottawa
Canada
K1H 8L6

Study participating centre
Hôpital Maisonneuve-Rosemont
5415 Assumption Blvd
Montreal
Canada
H1T 2M4

Sponsor information

Organisation
Royal Marsden NHS Foundation Trust

Sponsor details
Royal Marsden Hospital
Fulham Road
London
England
United Kingdom
SW3 6JJ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0008wzh48

Funder(s)

Funder type
Industry

Funder Name
Accuray Incorporated (USA)

Results and Publications

Publication and dissemination plan
The main trial results will be published in a peer-reviewed journal, on behalf of all collaborators. The manuscript will be prepared by a writing group, consisting of members of the Trial Management Group, and participating clinicians. All participating clinicians will be acknowledged in the publication.

All presentations and publications relating to the trial must be authorised by the Trial Management Group. Authorship of any secondary publications, e.g, will reflect the intellectual and time input into these studies. No Investigator may present or attempt to publish data relating to the PACE trial without prior permission from the Trial Management Group.

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article	acute toxicity findings	01/11/2019	20/06/2022	Yes	No
Plain English results			28/02/2023	No	Yes