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Partial prostate Ablation versus Radical prosTatectomy

Submission date	Recruitment status	[X] Prospectively registered
01/10/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/10/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/05/2023	Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-high-intensity-focused-ultrasound-or-surgery-treat-prostate-cancer-contained-one-part-prostate-gland-part

Study website
http://part.octru.ox.ac.uk/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 12/35/54

Study information

Scientific Title
A randomised controlled trial of Partial prostate Ablation versus Radical prosTatectomy (PART) in intermediate risk unilateral clinically localised prostate cancer - a feasibility study

Acronym
PART

Study objectives
The findings of an HTA systematic review 10/136/01: Ablative therapy for men with localised prostate cancer, which is due to publish shortly, conclude that the role of focal therapies in the management of men with localised prostate cancer should be investigated. It may be desirable to incorporate the focal approach into a multicentre RCT, with long-term follow-up and would include predefined assessment of cancer specific, dysfunction and health-related quality of life measures.

Our hypothesis is that a significant proportion of these patients would benefit from focal therapy with minimally invasive rather than radical procedures, with less morbidity, improved QoL, and reduced cost without compromising treatment effectiveness. If this can be established, ablative procedures could eventually replace conventional radical treatments in suitable patients and reduce the burden of treating the disease for the patients and the NHS.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/123554

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Berkshire, 22/12/2014

Study design
Prospective multi-centre parallel-group randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel 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
Prostate cancer

Interventions
Partial Ablation (PA) versus Radical prostatectomy (RP). Randomization is on a 1:1 basis and follow-up will be over 3 years:

In patients randomised to RP:
1. Routine removal of catheter at 10-14 days
2. Follow up in the clinic at six weeks post-surgery as per routine NHS care. This will include a PSA blood test and the following quesitonnaires will be presented to the patient:-
2.1. IIEF-15 Questionnaire
2.2. IPSS Questionnaire
2.3. UCLA-EPIC urinary continence and Bowel Questionnaire
2.4. EQ-5D-5L
2.5. FACT-P Version 4
2.6. The Modified 18-term Memorial Anxiety Scale for Prostate Cancer
2.7. Resource Utilisation Questionnaire
3. Followed up in the clinic every three months post-surgery in the first year and then every 6 months as per routine NHS care. PSA blood tests will be carried out every 3 months of 2 years. The following questionnaires will be presented to them at 3, 6, 9, 12, 18, 24, 30 and 36 months follow-up:
3.1. IIEF-15 Questionnaire
3.2. IPSS Questionnaire
3.3. UCLA-EPIC urinary continence and Bowel Questionnaire
3.4. EQ-5D-5L
3.5. FACT-P Version 4
3.6. The Modified 18-term Memorial Anxiety Scale for Prostate Cancer
3.7. Resource Utilisation Questionnaire
If at any point disease progression is suspected (rising PSA ≥0.2) the patient will be restaged.

In patients randomised to PA:
1. Routine removal of catheter at 7 days
2. Study specific care includes an mpMRI at two weeks
3. Followed up routinely at six weeks post-surgery as per routine NHS care. This will include a PSA blood test and the following questionniares will be presented to the patient:-
3.1. IIEF-15 Questionnaire
3.2. IPSS Questionnaire
3.3. UCLA-EPIC urinary continence and Bowel Questionnaire
3.4. EQ-5D-5L
3.5. FACT-P Version 4
3.6. The Modified 18-term Memorial Anxiety Scale for Prostate Cancer
3.7. Resource Utilisation Questionnaire
4. Followed up in the clinic every three months post-surgery for the first year and then every 6

months as per routine NHS care. PSA blood tests will be carried out every 3 months of 2 years. The following questionnaires will be presented to them at 3, 6, 9, 12, 18, 24, 30 and 36 months follow-up:
4.1. IIEF-15 Questionnaire
4.2. IPSS Questionnaire
4.3. UCLA-EPIC urinary continence and Bowel Questionnaire
4.4. EQ-5D-5L
4.5. FACT-P Version 4
4.6. The Modified 18-term Memorial Anxiety Scale for Prostate Cancer
4.7. Resource Utilisation Questionnaire
5. Study specific care includes an mpMRI at twelve months
6. Study specific care includes transrectal biopsies at twelve months
7. Study specific care includes an mpMRI at three years
8. Study specific care includes transrectal biopsies at three years

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measures as of 20/09/2016:
1. Randomisation of 80 participants within the proposed timelines
2. Uptake of randomisation of 50% among eligible and invited patients

Previous primary outcome measures:
1. Randomisation of 100 participants within the proposed timelines
2. Uptake of randomisation of 50% among eligible and invited patients

Secondary outcome measures
Added 07/03/2016:
Findings of the Qualitative Recruitment Investigation (QRI)

Overall study start date
01/01/2015

Completion date
01/01/2020

Eligibility

Key inclusion criteria
Current inclusion criteria as of 11/02/2016:
1. Men with unilateral clinically significant intermediate risk prostate cancer or dominant unilateral clinically significant intermediate risk & small contralateral low-risk disease:
1.1. Gleason grade score 7 (3+4 or 4+3)
1.2. High volume Gleason grade score 6 (> 4mm cancer core length)
1.3. PSA ≤ 20 ng/ml
1.4. Clinical ≤ T2b disease
2. Life expectancy of ≥10 years
3. Fit, eligible and normally destined for radical surgery
4. No concomitant cancer
5. No previous treatment of their prostate cancer

6. An understanding of the English language sufficient to understand written and verbal information about the trial, its consent process and the study questionnaires

Previous inclusion criteria:
1. Men with unilateral clinically significant intermediate risk prostate cancer:
1.1. Gleason grade score 7 (3+4 or 4+3)
1.2. And/or > 4mm cancer core length
1.3. PSA ≤ 20 ng/ml
1.4. - ≤ T2b disease
2. Fit and eligible for radical surgery
3. No concomitant cancer
4. No previous treatment of their prostate cancer

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
80

Key exclusion criteria
Current exclusion criteria as of 11/02/2016:
1. Unfit for radical surgery
2. Significant bilateral disease
3. Low risk disease [Gleason score 6 or less, PSA 10ng/ml]
4. High risk disease [Gleason score 8 or greater, PSA >20ng/ml]
5. Clinical T3 disease
6. Men who have received previous active therapy for prostate cancer
7. Men with evidence of extra prostate disease
8. Men with an inability to tolerate a transrectal ultrasound
9. Men with latex allergy
10. Men who have undergone a Transurethral Resection of the Prostate (TURP) for symptomatic lower urinary tract symptoms within 6 months.
11. Metal implants/stents in the urethra
12. Prostatic calcification and cysts which interfere with effective delivery of HIFU
13. Men with renal impairment and a GFR <35ml/min
14. Unable to give consent to participate in the trial as judged by the attending clinicians

Previous exclusion criteria:
1. Unfit for radical surgery as assessed by Consultant Anaesthetist
2. Significant bilateral disease
3. Low risk disease [Gleason score 6 or less, PSA 10ng/ml or less, less than 4mm total cancer on biopsy]
4. High risk disease [Gleason score 8 or greater, PSA >20ng/ml, T2c stage or higher]
5. Men who have had previous radiation therapy
6. Men who have had androgen suppression/hormone treatment within the previous 12 months

for their prostate cancer
7. Men who have had previous HIFU, cryosurgery, thermal or microwave therapy to the prostate.
8. Men with evidence of metastatic disease or nodal disease outside the prostate on bone scan or cross-sectional imaging
9. Men with an inability to tolerate a transrectal ultrasound or men with latex allergies as the HIFU probe is covered with a latex condom sheath prior to insertion into the back passage
10. Men who have undergone prior significant rectal surgery preventing insertion of trans-rectal HIFU probe (decided on the type of surgery in individual cases)
11. Men who have undergone a Transurethral Resection of the Prostate (TURP) for symptomatic lower urinary tract symptoms within 6 months. These patients may be included within the trial if deferred from consenting and screening until at least 6 months following the TURP.
12. Presence of metal implants/stents in the urethra
13. Presence of prostatic calcification and cysts (on transrectal ultrasound) whose location will interfere with effective delivery of HIFU therapy
14. Men with renal impairment with a GFR of <35ml/min (unable to tolerate Gadolinium dynamic contrast enhanced MRI)
15. Unable to provide informed consent (eg because of cognitive impairment)

Date of first enrolment
01/01/2015

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Churchill Hospital
Oxford
United Kingdom
OX3 7LE

Study participating centre
Royal Hallamshire Hospital
Sheffield
United Kingdom
S10 2JF

Study participating centre

Basingstoke & North Hampshire Hospitals
Basingstoke
United Kingdom
RG24 9NA

Study participating centre
Southampton General Hospital
Southampton
United Kingdom
SO16 6YD

Study participating centre
University College Hospital
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
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Sponsor details
Joint Research Office
Block 60
Churchill Hospital
Old Road
Headington
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United Kingdom
OX3 7LE
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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
01/01/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2018		Yes	No
Plain English results			11/05/2023	No	Yes