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Radiofrequency ablation focal treatment

Submission date 04/03/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/03/2015	**Overall study status** Completed	
Last Edited 28/05/2019	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-of-radiofrequency-ablation-to-treat-cancer-in-the-prostate-gland-pro-raft

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT02294903

Protocol serial number
TM-105

Study information

Scientific Title
A prospective development study evaluating focal therapy using encage coiled bipolar radiofrequency ablation in men with localised prostate cancer

Acronym
ProRAFT

Study objectives
For men with localised prostate cancer when treating only the areas of cancer with a coiled radiofrequency based bipolar device, this can lead to a more precise and better controlled ablation minimising side effects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Riverside

Study design
Prospective development study (IDEAL Surgery Guidelines)

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Coiled bipolar radiofrequency ablation for men with histologically proven localized prostate cancer which is clinically significant. Localization and characterization of the disease will be established using multi-parametric (mp)-MRI and transperineal prostate biopsies. Pre-operative and all post operative imaging will be performed using a scanner and a pelvic phased array receiver, with a pelvic coil. The process will involve targeted or mapping biopsies which are concordant with the lesion seen on MRI. In both cases, transperineal biopsies will be taken from the prostate using a brachytherapy grid placed over the perineal skin whilst the man is in the lithotomy position. The evaluation will be done 6 months later by determining the ablative efficacy of focal therapy to treat localized low to intermediate risk prostate cancer.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Ablative efficacy of focal therapy to treat localised low to intermediate risk prostate cancer using Coiled Bipolar Radiofrequency Ablation (Encage™), using histological outcomes (Disease control: 6 months histology treated area - Proportion of men with clinically significant prostate cancer on targeted transperineal biopsy in the treated area)

Key secondary outcome(s))
1. Rate of any prostate cancer on targeted transperineal biopsy in the treated area
2. Rate of achievement of trifecta status (no severe Erectile Dysfunction (ED), pad-free leak-free continence, cancer control with no evidence of clinically significant cancer in treated area) at 6 months in those men with good baseline function

3. Rate of achievement of trifecta status (no severe Erectile Dysfunction (ED), pad-free continence, cancer control with no evidence of clinically significant cancer in treated area) at 6 months in those men with good baseline function
4. Time to initiation of secondary prostate cancer intervention (prostatectomy, radiotherapy, androgen ablation, focal/whole gland High Intensity Focused Ultrasound (HIFU) or cryosurgery) as a result of:
4.1. Histological burden greater than Gleason pattern 3 and/or max Cancer Core Length Involvement (CCLI) >/=3mm
4.2. Rising Prostate Specific Antigen (PSA) (needs Trial Steering Committee validation of clinical, pathological and case report form review to verify reason)
5. Time to initiation of secondary prostate cancer intervention (prostatectomy, radiotherapy, androgen ablation,focal/whole gland High Intensity Focused Ultrasound (HIFU) or cryosurgery) for any cause

Completion date
30/11/2016

Eligibility

Key inclusion criteria
1. Histologically proven prostate cancer
2. A visible lesion on mpMRI, that is accessible to a treatment based on radiofrequency bipolar electrodes
3. Transperineal prostate biopsies (template mapping and/or targeted)correlating with clinically significant lesion in the area of the MR-visible lesion
4. Absence of clinically significant histological disease outside of the planned treatment zone
5. Radiological stage T1-T3 a N0 M0 disease, as determined by local guidelines
6. Serum PSA </=15ng/ml within 3 months of screening visit
7. Life expectancy of more than 10 years
8. Signed informed consent by patient
9. An understanding of the English language sufficient to understand written and verbal information about the trial and consent process

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Total final enrolment
21

Key exclusion criteria

1. Men who have had previous radiation therapy to the pelvis
2. Men who have had androgen suppression/hormone treatment within the previous 12 months for their prostate cancer
3. Men with evidence of metastatic disease or nodal disease outside the prostate on bone scan or cross-sectional imaging
4. Men with a tumour not visible on mpMRI
5. Men with an inability to tolerate a transrectal ultrasound
6. Men allergic to latex
7. Men who have undergone prior significant rectal surgery preventing insertion of the TRUS probe (decided on the type of surgery in individualcases)
8. Men who have had previous electroporation, radiofrequency ablation, HIFU,cryosurgery, thermal or microwave therapy to the prostate
9. Men who have undergone a Transurethral Resection of the Prostate(TURP) for symptomatic lower urinary tract symptoms within the prior 6months. These patients may be included within the trial if deferred fromconsent and screening until at least 6 months following the TURP
10. Men not fit for major surgery as assessed by a Consultant Anaesthetist
11. Men unable to have pelvic MRI scanning (severe claustrophobia,permanent cardiac pacemaker, metallic implant etc likely to contribute significant artefact to images)
12. Presence of metal implants/stents in the urethra
13. Men with renal impairment with a GFR of <35ml/min (unable to tolerate Gadolinium dynamic contrast enhanced MRI)

Date of first enrolment
13/03/2015

Date of final enrolment
31/03/2016

Locations

Countries of recruitment
United Kingdom

Study participating centre
NHS GP practices in the UK
United Kingdom
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Sponsor information

Organisation
TROD Medical

Funder(s)

Funder type
Industry

Funder Name
TROD Medical (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	results presented at EAU18 Copenhagen in :	01/03/2018	16/04/2019	No	No