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SABRE 1: Surgery Against Brachytherapy - a Randomised Evaluation

Submission date 11/03/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/05/2008	**Overall study status** Completed	
Last Edited 14/02/2020	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-study-looking-at-giving-men-with-prostate-cancer-a-dvdvideo-on-treatment-for-prostate-cancer-and-the-possibility-of-a-study-comparing-2-different-treatments-for-prostate-cancer

Study website
http://www.ctu.soton.ac.uk/trial.aspx?trialid=8

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT01098331

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomised controlled trial of brachytherapy versus radical prostatectomy in good risk prostate cancer: a feasibility study

Acronym
SABRE 1

Study objectives
1. In men with localised prostate cancer, will the addition of a decision aid to standard information improve accrual to a randomised trial of radical prostatectomy versus brachytherapy?
2. Is it feasible to perform a phase III randomised controlled trial of brachytherapy versus radical prostatectomy in men with localised prostate cancer?

Ethics approval required
Old ethics approval format

Ethics approval(s)
To be submitted to Southampton & South West Hampshire Research Ethics Committee in May 2008 – pending

Study design
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 below to request a patient information sheet

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

Interventions
This trial includes two stages of randomisation.

Randomisation 1: Participants are initially randomised to either receive standard patient information or to receive the standard patient information plus the decision aid. The decision aid is a DVD or video that the participant is able to watch at home.

Randomisation 2: Participants that then choose to enter the treatment randomisation stage will be randomised to undergo either radical prostatectomy or brachytherapy.

Radical prostatectomy: The surgical technique may be either open or retropubic and will take place within 60 days of randomisation. Pelvic lymph node surgery is permitted at the discretion of the treating surgeon. Unilateral or bilateral nerve sparing techniques may also be used at the discretion of the surgeon.

Brachytherapy: Will be performed within 60 days of randomisation. It will be performed under general or regional anaesthesia. Intravenous antibiotic coverage such as gentamycin is recommended at induction of anaesthetic. In addition oral ciprofloxacin 500 mg twice a day (bd) for 7 days is recommended. Transrectal ultrasound probe attached to a stabilised stepping unit should be used. Planning must be via transrectal ultrasound. The urethra should be visualised using aerated gel in a catheter. The isotope to be used is either iodine-125 or palladium-103. Seeds may be implanted using pre-loaded needles or a MICK applicator. For palladium-103 the dose will be 125.00 Gy, minimum peripheral dose. For iodine-125 the minimum peripheral dose will be 145.00 Gy. Peripheral loading is advisable to limit the dose to the urethra to less than or equal to 150% of the prescribed dose. The seed activity for palladium-103 is 1-1.6 millicuries and for iodine-125 is 0.28-0.5 millicuries per seed.

Intervention Type
Mixed

Primary outcome measure
Decision aid randomisation:
Proportion of patients consenting to the treatment randomisation

Treatment randomisation:
Feasibility of randomisation in terms of average accrual rate per centre during the last 6 months of recruitment.

Secondary outcome measures
Decision aid randomisation:
Decisional quality post-treatment

Treatment randomisation:
1. Compliance with allocated treatment
2. Clinical failure. Duration of follow-up: 10 years
3. PSA relapse. Duration of follow-up: 10 years
4. Patient-reported quality of life at 5 years (see below for details)
5. Toxicity. Duration of follow-up: 10 years

Quality of life will be measured using a 50-question document to include the following:
a. The 12-item short form health survey (SF-12; General quality of life)

b. European Quality of Life questionnaires (EQ-5D; General quality of life to tie in with health economic data)
c. The International Continence Society 'male short-form' (ICSmaleSF) questionnaire (urinary functioning)
d. Vaizey Questionnaire (A short, validated bowel function questionnaire)
e. The International Index of Erectile Function (IIEF5)

The questionnaires will be amalgamated into one single 50-question document which will be administered as a single questionnaire at each assessment point. Quality of Life questionnaire compliance will be carefully monitored during this feasibility trial; this and clinical outcomes will be used as one basis for the sample size calculation for the SABRE 2 phase III trial.

Overall study start date
01/06/2008

Completion date
01/06/2013

Eligibility

Key inclusion criteria
1. Suspected prostate cancer that is confined to the prostate
2. Due for prostate biopsy
3. World Health Organisation performance status 0 - 1
4. Prostate-Specific Antigen (PSA) less than 15 ng/ml
5. Life expectancy more than 10 years
6. Written informed consent

Inclusion criteria for treatment randomisation:
1. Participation in decision aid randomisation
2. Histologically confirmed prostate cancer
3. Clinical T stage T1/T2
4. Either Gleason score less than or equal to 6 with a PSA of less than 15 or Gleason score 3 + 4 in less than 50% of the cores with a PSA less than 10 (PSA test less than 3 months prior to treatment intervention)

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
400

Key exclusion criteria

1. Unacceptable risk for radical prostatectomy
2. Unacceptable risk for brachytherapy
3. Prior pelvic radiotherapy
4. Other active malignancy likely to interfere with subsequent protocol treatment and follow-up
5. Previous abdominoperineal (AP) rectal excision
6. Previous transurethral resection of their prostate gland (TURP)
7. Significant obstructive urinary symptoms (peak urine flow rate less than 10 ml per second, post micturition bladder volume greater than 75 ml)
8. Severe lower urinary tract symptoms
9. Inability to attend or comply with treatment or follow-up scheduling

Date of first enrolment
01/06/2008

Date of final enrolment
01/06/2013

Locations

Countries of recruitment
Canada

England

United Kingdom

Study participating centre
St. James' University Hospital
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Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.suht.nhs.uk

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Plain English results				No	Yes
Results article	results	01/08/2013		Yes	No