

# SABRE 1: Surgery Against Brachytherapy - a Randomised Evaluation

<b>Submission date</b> 11/03/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/05/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/02/2020	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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>

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### ClinicalTrials.gov (NCT)

NCT01098331

### Protocol serial number

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

## **Study type(s)**

Treatment

## **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(s)**

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.

## **Key secondary outcome(s)**

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.

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Male

### **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**

United Kingdom

England

Canada

**Study participating centre**  
**St. James' University Hospital**  
Leeds  
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## Sponsor information

**Organisation**  
Southampton University Hospitals NHS Trust (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, Cancer Research UK (CRUK), CRUK

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Other non-profit organizations

**Location**  
United Kingdom

## Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/08/2013		Yes	No
<a href="#">Plain English results</a>				No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes