

# Open prostatectomy versus laparoscopic prostatectomy versus robot-assisted prostatectomy for organ-confined prostate cancer

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>20/10/2009   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>12/01/2010 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>25/10/2024       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data                                              |

## Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/a-trial-comparing-three-operations-for-prostate-cancer>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

## Study information

### Scientific Title

Randomised controlled trial of laparoscopic, open and robot assisted prostatectomy as treatment for organ-confined prostate cancer

### Acronym

LopeRA

### Study objectives

This study will demonstrate the feasibility of patient recruitment to a randomised controlled trial comparing open, laparoscopic and robot-assisted radical prostatectomy.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

East London City Research Ethics Committee (REC), 23/12/2009, ref: 09/H0704/70

### Study design

Multicentre randomised feasibility study for a phase III randomised controlled trial

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Prostate cancer

### Interventions

There are three groups:

1. Open prostatectomy
2. Laparoscopic prostatectomy
3. Robot-assisted prostatectomy

### Intervention Type

Other

### Phase

Phase III

### Primary outcome(s)

Accrual rate: aim to recruit more than 100 patients with at least 75 patients within a 12-month period (e.g. between 12 and 24 months after all centres are open to recruitment).

### Key secondary outcome(s)

1. Compliance with protocol: a compliant patient will be defined as one who receives their allocated treatment and the in-patient standardised peri-operative care. We aim to show that more than 80% are compliant.
2. Clinical and patient-orientated outcomes:
  - 2.1. Operation duration
  - 2.2. Blood loss
  - 2.3. Transfusion rates
  - 2.4. Peri-operative haemoglobin change
  - 2.5. Operative complications
  - 2.6. Length of hospital stay
  - 2.7. Pathological specimen positive margin rates and biochemical progression-free rates
  - 2.8. Sexual function
  - 2.9. Urinary continence
  - 2.10. Quality of life measures

All patients are followed up for 12 months.

### **Completion date**

30/09/2011

## **Eligibility**

### **Key inclusion criteria**

1. Prostate cancer patient that has chosen radical prostatectomy as treatment (with or without lymphadenectomy)
2. Clinical stage T1, T2a, T2b or T2c, N0 M0
3. Gleason score less than or equal to 7
4. Prostate-specific antigen (PSA) less than or equal to 20
5. Aged greater than or equal to 18 years, male
6. Written informed consent

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

Male

### **Key exclusion criteria**

1. Patient medically unfit for surgery
2. Prior pelvic radiotherapy or rectal excisional surgery
3. Positive bone scan or evidence of nodal metastases on magnetic resonance imaging (MRI) or

computed tomography (CT)  
4. Clinical stage T3  
5. Neoadjuvant hormone therapy

**Date of first enrolment**

01/10/2009

**Date of final enrolment**

30/09/2011

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**St Mary's Hospital**

London

United Kingdom

W2 1NY

## Sponsor information

**Organisation**

Imperial College London (UK)

**ROR**

<https://ror.org/041kmwe10>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Cancer Research UK (CRUK) (UK) (ref: CRUK/09/008)

**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="#">Abstract results</a> | results | 12/07/2014   |            | No             | No              |
| <a href="#">Basic results</a>    |         |              | 25/10/2024 | No             | No              |