

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

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

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

ICR-CTSU/2009/10021

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

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

There are three groups:

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

Intervention Type

Other

Phase

Phase III

Primary outcome measure

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).

Secondary outcome measures

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.

Overall study start date

01/10/2009

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

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

100

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**

England

United Kingdom

Study participating centre

St Mary's Hospital

London

United Kingdom

W2 1NY

Sponsor information**Organisation**

Imperial College London (UK)

Sponsor details

G02, Sir Alexander Fleming Building

South Kensington Campus

London

England
United Kingdom
SW7 2AZ

Sponsor type

University/education

Website

<http://www3.imperial.ac.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, 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?
Abstract results	results	12/07/2014		No	No
Basic results			25/10/2024	No	No