ISRCTN59410552 https://doi.org/10.1186/ISRCTN59410552

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

Submission date
20/10/2009

Recruitment status
No longer recruiting

Registration date
12/01/2010

Overall study status
Completed

Last Edited
25/10/2024

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Prof Ara Darzi

Contact details
St Mary's Hospital
10th Floor QEQM Building
South Wharf Road
London
United Kingdom
W2 1NY

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