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Comparison between laparoscopic (keyhole surgery) and robot-assisted surgery for patients with prostate cancer

Submission date	Recruitment status	[_] Prospectively registered
03/04/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/06/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/04/2024	Surgery	

Plain English summary of protocol

Background and study aims
Radical prostatectomy (RP; a surgical procedure that removes the prostate gland and attached seminal vesicles) is a common treatment for patients with clinically localised prostate cancer (PCa) and a life expectancy greater than 10 years. Surgery is traditionally performed by open retropubic RP, although laparoscopic (keyhole) RP (LRP) and especially robot-assisted RP (RARP) have become popular in the last 15 years. Although the advantages of laparoscopy over open surgery, at least in terms of minimal invasiveness, are well known, LRP and RARP have rarely been compared. The primary objective of the study is to compare the safety and efficacy of the laparoscopic and robot-assisted techniques in radical prostatectomy surgery by analysing peri-operative and follow-up data from patients operated using these techniques at San Luigi Gonzaga Hospital (Orbassano, Italy).

Who can participate?
Men between 50 and 75 years of age with localised or locally advanced prostate cancer

What does the study involve?
Participants who meet the inclusion criteria and are willing to undergo surgery are asked to join this study. Participants are randomly allocated to one of two groups:
- group A: will undergo LRP
- group B: will undergo RALP
Patients are followed up for 10 years

What are the possible benefits and risks of participating?
Recently, several studies have been published on the use of RARP, which have confirmed results comparable to LRP in terms of mini-invasiveness and encouraging results in terms of functional outcomes. Literature suggests RARP decreases bleeding, shortens the length of hospital stay, and decreases the readmission and total perioperative complication rates compared with other approaches without impairing the oncologic outcome. For these reasons, patients randomized

to the two groups may differ in intra- and postoperative complications, recovery of urinary continence and erectile function, and oncological outcome depending on the surgical technique they underwent.

Where is the study run from?
The study is being run from San Luigi Gonzaga Hospital, Orbassano (Turin), Italy

When is the study starting and how long is it expected to run for?
Octover 2009 to January 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Francesco Porpiglia
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
136/2009

Study information

Scientific Title
Comparison of laparoscopic and robot-assisted radical prostatectomy for patients with localized prostate cancer: analysis of benefits and complications in a prospective randomised study

Study objectives
The aim of the study is to compare the safety and efficacy of the laparoscopic and robot-assisted techniques in radical prostatectomy surgery by analysing peri-operative and follow-up data from patients operated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/10/2009, San Luigi Gonzaga Hospital Ethics committee (Regione Gonzole 10, Orbassano, Turin, Italy; +39 0119026204; sperimentazioni@sanluigi.piemonte.it), ref: N 136/2009

Study design
Single-centre interventional randomized parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Surgical treatment of localized prostate cancer

Interventions
All patients who are candidates for radical prostatectomy will be randomised into two groups:
- Group A: will undergo laparoscopic radical prostatectomy (LRP);
- Group B: will undergo robot-assisted radical prostatectomy (RALP).
A two-armed randomisation scheme will be generated by means of a specific "query" to the website www.randomization.com. A typical video laparoscopic radical prostatectomy with a transperitoneal approach will be performed. When necessary extended pelvic lymphadenectomy will be associated. Both groups will be treated with the same anaesthesia protocol both intraoperatively (general anaesthesia) and immediately after surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Postoperative urinary continence will be assessed with ICS questionnaire at 1, 3, 6, 12, 60 and 120 months after surgery.
2. Postoperative erectile function will be assessed with IIEF5 questionnaire at 1, 3, 6, 12, 60 and 120 months after surgery.

Secondary outcome measures
1. Serum PSA levels will be assessed at 1, 3, 6, 12, 60 and 120 months after surgery
2. Intraoperative complications will be assessed using Clavien-Dindo scale during the intervention
3. Postoperative complications will be assessed using Clavien-Dindo scale at 1, 12, 60 and 120 months after surgery

Overall study start date
01/10/2009

Completion date
01/01/2022

Eligibility

Key inclusion criteria
1. Aged between 50 and 75 years
2. Diagnosed with localised or locally advanced prostate adenocarcinoma (clinical stage T1-2 or T3, in each case N0, M0)
3. Gleason score between 2 and 10
4. PSA <20ng/ml

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
100

Total final enrolment
120

Key exclusion criteria
Patients who withdraw consent

Date of first enrolment
01/01/2010

Date of final enrolment

01/01/2011

Locations

Countries of recruitment
Italy

Study participating centre
San Luigi Gonzaga Hopsital
Regione gonzole 10
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Sponsor information

Organisation
University of Turin

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Sponsor type
University/education

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ROR
https://ror.org/048tbm396

Funder(s)

Funder type
Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/06/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to authors' elect. The data will be held by the corresponding author.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/07/2012	21/04/2022	Yes	No
Results article	Ten-year follow up	04/04/2024	04/04/2024	Yes	No