

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

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<b>Registration date</b> 10/06/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/04/2024	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## 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?

October 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

### Contact name

Prof Francesco Porpiglia

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

### **Study type(s)**

Treatment

### **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](http://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(s)**

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.

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

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Male

**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 Hospital  
Regione gonzole 10

Orbassano (Turin)  
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10043

## Sponsor information

### Organisation

University of Turin

### ROR

<https://ror.org/048tbm396>

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded

## Results and Publications

### 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?
<a href="#">Results article</a>		20/07/2012	21/04/2022	Yes	No
<a href="#">Results article</a>	Ten-year follow up	04/04/2024	04/04/2024	Yes	No