# An innovative approach for robotic-assisted laparoscopic radical prostatectomy: a single-hospital study

| Submission date   | Recruitment status   | <ul><li>Prospectively registered</li></ul>    |
|-------------------|----------------------|---|
| 11/08/2023        | No longer recruiting | Protocol                                      |
| Registration date | Overall study status | Statistical analysis plan                     |
| 30/08/2023        | Completed            | Results                                       |
| Last Edited       | Condition category   | [] Individual participant data                |
| 23/08/2023        | Surgery              | <ul><li>Record updated in last year</li></ul> |

# Plain English summary of protocol

Background and study aims

Robot-assisted laparoscopic radical prostatectomy (RARP) is a surgical treatment for prostate cancer patients without metastasis (when the cancer hasn't spread). Injury of the nerve near the prostate during the operation could lead to incontinence or erectile disability. The pubovesical complex-sparing RARP technique can preserve essential nerves for urine and sexual function better. This study aimed to describe the steps of the pubovesical complex-sparing laparoscopic RARP technique and report the functional and oncological outcomes.

#### Who can participate?

Clinically localized prostate cancer patients aged between 18 and 70 years

#### What does the study involve?

All patients received pubovesical complex-sparing laparoscopic RARP. Personal data including urine and sexual function is recorded before the operation. The surgical outcome was recorded after the operation. The treatment course was the same as other prostate cancer patients. The only difference was the surgical method.

What are the possible benefits and risks of participating?

A benefit is that the outcome of pubovesical complex-sparing laparoscopic RARP is expected to achieve an international level. There are no major complications.

Where is the study run from?

Tungs' Taichung MetroHarbor Hospital (Taiwan)

When is the study starting and how long is it expected to run for? January 2019 to December 2022

Who is funding the study?

Tungs' Taichung MetroHarbor Hospital (Taiwan)

Who is the main contact?
Chin-Heng, Lu, chinhenglu@gmail.com (Taiwan)

# Contact information

## Type(s)

**Public** 

#### Contact name

Dr Chin-Heng Lu

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# Additional identifiers

# Clinical Trials Information System (CTIS)

Nil known

# ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

Nil known

# Study information

#### Scientific Title

Pubovesical Complex-sparing Technique during Robotic-assisted Laparoscopic Radical Prostatectomy functional and oncologic outcomes report: a single-institution case series

#### Acronym

Modified PCS RARP

## Study objectives

This study aimed to describe the steps of the PVC-sparing technique and report functional and oncological outcomes.

# Ethics approval required

Ethics approval required

#### Ethics approval(s)

approved 15/04/2020, Institutional Review Board of Tungs' Taichung Metroharbor Hospital (No. 699, Section 8, Taiwan Boulevard, Wuqi District, Taichung City, 43503, Taiwan; +886-4-26581919#4635; d3905@ms3.sltung.com.tw), ref: 109007

#### Study design

Single-institution case series observational report for 2 years

## Primary study design

Observational

#### Study type(s)

Treatment

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

Surgical skill introduction and surgical outcome report for clinically localized prostate cancer patients with specific surgical treatment

#### **Interventions**

Surgical skill introduction and surgical outcome report for patients who received pubovesical complex-sparing robotic-assisted laparoscopic radical prostatectomy.

#### Intervention Type

Procedure/Surgery

#### Primary outcome(s)

Erectile function measured using the International Index of Erectile Function (IIEF)-5 score preoperatively and at follow-up for at least 2 years

# Key secondary outcome(s))

There are no secondary outcome measures

# Completion date

31/12/2022

# **Eligibility**

#### Key inclusion criteria

- 1. Male patients aged over 18 years and <70 years
- 2. Clinically organ-confined disease (cT1-cT2) staged by CT scan
- 3. Gleason score ≤7
- 4. Total PSA ≤10 ng/mL. PSA or biochemical failure was defined as two serial serum PSA results >0.2 ng/mL
- 5. Prostate volume <60 mL
- 6. Normal preoperative continence and sexual function. Patients had to be completely continent (pad-free) and have an IIEF score ≥17 at baseline. Continence was defined as not using pads. Potency was defined as achieving full erection during sexual intercourse with or without using phosphodiesterase 5 inhibitors (PDE5-Is).

## Participant type(s)

#### Patient

# Healthy volunteers allowed

No

## Age group

Mixed

#### Lower age limit

18 years

#### Upper age limit

70 years

#### Sex

Male

#### Total final enrolment

33

# Key exclusion criteria

- 1. Neoadjuvant hormonal therapy
- 2. Previous prostate, urethra, or bladder neck surgery
- 3. Bilateral NVBs were not preserved
- 4. Salvage RALP
- 5. Anteriorly located tumours

#### Date of first enrolment

01/01/2019

#### Date of final enrolment

30/09/2020

# Locations

# Countries of recruitment

Taiwan

# Study participating centre Tungs' Taichung MetroHarbor Hospital

No.699, Sec. 8, Taiwan Blvd Taichung City Taiwan 43503

# Sponsor information

## Organisation

Tungs' Taichung MetroHarbor Hospital

#### **ROR**

https://ror.org/0452q7b74

# Funder(s)

#### Funder type

Hospital/treatment centre

#### **Funder Name**

Tungs' Taichung MetroHarbor Hospital

#### Alternative Name(s)

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

Other non-profit organizations

#### Location

Taiwan

# **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 ethical and legal restrictions.

# IPD sharing plan summary

Not expected to be made available

# Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet
Participant information sheet
11/11/2025 No Yes