

Effect of a modified technique of urinary reconstruction during radical prostatectomy on early continence: a randomized controlled trial

Submission date 03/07/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 03/07/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/08/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The aim of the study was to evaluate whether a modification to the current technique of reconstruction during radical prostatectomy could improve early recovery of urinary continence after surgery.

Who can participate?

All patients undergoing this surgery could participate unless they had conditions that could also impact urinary continence.

What does the study involve?

The study involves adding a suspensory suture to provide additional support to the urethra or using the standard technique without this additional suture.

What are the possible benefits and risks of participating?

The possible benefits were an earlier recovery of socially acceptable continence after surgery while the risks were minimal and could in theory include urinary retention and pain after the surgery.

Where is the study run from?

Centre Hospitalier Universitaire de Québec (Canada)

When is the study starting and how long is it expected to run for?

August 2018 to March 2020

Who is funding the study?

Fondation CHU de Québec (Canada)

Who is the main contact?

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Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CER-CHUQ 2019-4193

Study information

Scientific Title

Effect of a modified technique of posterior reconstruction by iliopectineal ligament suspension during robot-assisted laparoscopic radical prostatectomy on early continence: a randomized controlled trial

Study objectives

A modified posterior urethral support would aim to recreate a suspensory mechanism to enhance early continence by reducing urethral mobility and restoring a normal urethra-vesical angle during increases in abdominal pressure.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 26/06/2018, Comité d'éthique de la recherche du CHU de Québec-Université Laval (11, côte du Palais, Québec, G1R 2J6, Canada; +1 4185254444; ethiquedelarecherche@chudequebec.ca), ref: CER-CHUQ 2019-4193

Study design

Single center single surgeon single-blinded randomized trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Prostate cancer

Interventions

Posterior reconstruction was done using a standard technique in the control group and was modified for the experimental group by incorporating not only the "Rocco" stitch between Denonvilliers' fascia and the rhabdosphincter but also the iliopectineal ligaments bilaterally to further improve posterior support with this suspensory 'hammock'. Both groups of patients were followed for a year with periodic questionnaires and 24-hour pad tests.

Randomization:

Sealed envelope before surgery, randomised preoperatively by randomisation software.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Recovery of continence after prostatectomy measured using Expanded Prostate cancer Index Composite (EPIC-26) questionnaire sent at 1, 3, 6 and 12 months post-operatively

Key secondary outcome(s))

Measured at 1, 3, 6 and 12 months post-operatively:

1. Long term continence measured using Expanded Prostate cancer Index Composite (EPIC-26) questionnaire
2. Erectile function measured using Erectile Function (IIEF-5)
3. Severity of SUI measured using 24-hour pad test at 3, 6 and 12 months

Completion date

31/03/2020

Eligibility**Key inclusion criteria**

Localised prostate cancer staged with conventional imaging who chose to be treated with radical prostatectomy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

40 years

Upper age limit

85 years

Sex

Male

Total final enrolment

171

Key exclusion criteria

1. Patients with clinical stage T4
2. Neoadjuvant hormonotherapy
3. Previous history of radiation therapy
4. Endoscopic or open surgeries of the prostate
5. Urethral stricture
6. Urinary incontinence
7. Neurologic disease

Date of first enrolment

01/08/2018

Date of final enrolment

31/03/2020

Locations**Countries of recruitment**

Canada

Study participating centre

Hôtel-Dieu de Québec Hospital

11, côte du Palais

Québec

Canada

G1R 2J6

Sponsor information**Organisation**

Centre Hospitalier Universitaire de Québec

ROR

Funder(s)

Funder type
Charity

Funder Name
Fondation CHU de Québec

Alternative Name(s)
CHUQ Foundation, Fondation CHUQ

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Canada

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 limitations from the consent obtained from participants

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		21/07/2024	02/08/2024	Yes	No
Participant information sheet	version 2	19/06/2018	03/07/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			03/07/2024	No	No