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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

Registration date
03/07/2024

Overall study status
Completed

Last Edited
02/08/2024

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 additionnal 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?
kaleem.atchia.1@ulaval.ca

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Mr Kaleem Atchia

Contact details
11, côte du Palais
Québec
Canada
G1R 2J6
+1 4185254444
kaleem.atchia.1@ulaval.ca

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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 measure
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

Secondary outcome measures
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

Overall study start date
01/08/2018

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

Age group
Adult

Lower age limit
40 Years

Upper age limit
85 Years

Sex
Male

Target number of participants
200

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

Sponsor details
11, côte du Palais
Québec
Canada
G1R 2J6
+1 4185254444
chu@chudequebec.ca

Sponsor type
Hospital/treatment centre

Website
https://www.chudequebec.ca/accueil.aspx

ROR
https://ror.org/006a7pj43

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

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

Intention to publish date
15/07/2024

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?
Participant information sheet	version 2	19/06/2018	03/07/2024	No	Yes
Protocol file			03/07/2024	No	No
Results article		21/07/2024	02/08/2024	Yes	No