

Pain relief provided by a caudal epidural following robotic surgery removing the prostate while under general anaesthesia

Submission date 28/04/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/04/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 29/04/2025	Condition category Surgery	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This study is looking at how effective a pain-relieving injection, called a caudal block, is for patients having robotic-assisted surgery to remove the prostate gland. The aim is to see if this injection can help reduce pain after the surgery and lessen the need for stronger painkillers like morphine.

Who can participate?

Patients who are scheduled to have robotic-assisted prostate surgery at Galway University Hospital can participate in this study.

What does the study involve?

Participants will be randomly divided into two groups. One group will receive the standard pain relief methods, while the other group will receive an additional caudal block injection. This injection is given while the patient is under general anaesthetic and helps numb the lower half of the body.

What are the possible benefits and risks of participating?

The possible benefits include better pain relief after surgery and a quicker recovery. The risks are minimal but may include side effects from the caudal block, such as temporary numbness or discomfort.

Where is the study run from?

Galway University Hospital (Ireland)

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

June 2023 to December 2023.

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Eoin Coughlan, eoin645@outlook.com

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Dr Patrick Neligan, pjneligan@yahoo.com

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Additional identifiers

Protocol serial number
CA 3049

Study information

Scientific Title

Analgesic requirements following caudal epidural in elective robotic prostatectomy

Study objectives

Caudal epidural decreases post-operative opioid analgesic requirements in robotic prostatectomy as opposed to protocolled multimodal analgesia alone

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 06/07/2023, Galway University Hospital Ethics Committee (Newcastle Road, Galway, H91 YR71, Ireland; +353 91524222; consumeraffairs.west@hse.ie), ref: CA 3049

Study design

Randomised single-blinded controlled trial

Primary study design

Interventional

Study type(s)

Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied

Robotic prostatectomy

Interventions

General anaesthesia for the procedure will be standardised and include the administration of abdominal wall blocks and morphine. The study intervention is to administer an additional caudal epidural block to patients randomised into the intervention group. The patients who are administered standard anaesthesia will henceforth be called the 'control' group.

Candidates will be randomised into 2 groups. This will be done by the last digit of the patient's board number. The candidates with an even final digit of their board number will be considered for caudal block. The candidates with an odd final digit will not be given a caudal block.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Cumulative opioid consumption in the 24 hour post-operative period measured using patient records

Key secondary outcome(s)

1. Pain (visual analogue) score at 2, 4, 6, and 24 hours post-procedure
2. Cumulative requirements for anti-emetic therapy in the first 24 hours post-operatively
3. Richmond Agitation-Sedation Score at 2, 4, 6, and 24 hours post-procedure

Completion date

31/12/2023

Eligibility

Key inclusion criteria

Those undergoing elective radical robotic prostatectomy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

25 years

Upper age limit

90 years

Sex

Male

Total final enrolment

70

Key exclusion criteria

1. Participant refusal
2. Treatment for chronic pain
3. Psychiatric illness
4. Local pathology of the spine

Date of first enrolment

12/06/2023

Date of final enrolment

13/12/2023

Locations

Countries of recruitment

Ireland

Study participating centre

Galway University Hospital

Newcastle Road

Galway

Ireland

H91 YR71

Sponsor information

Organisation

Ollscoil na Gaillimhe – University of Galway

ROR

<https://ror.org/03bea9k73>

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 will be available upon request from Eoin Coughlan - eoin645@outlook.com

IPD sharing plan summary

Available on request