

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

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<b>Registration date</b> 29/04/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 29/04/2025	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input checked="" 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

## Contact information

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
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

**Secondary study design**  
Randomised controlled trial

**Study setting(s)**  
Hospital

**Study type(s)**  
Quality of life, Treatment, Efficacy

**Participant information sheet**  
Not available in web format, please use contact details to request a participant information sheet

## **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 measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

01/06/2023

## **Completion date**

31/12/2023

# **Eligibility**

## **Key inclusion criteria**

Those undergoing elective radical robotic prostatectomy

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

25 Years

## **Upper age limit**

90 Years

## **Sex**

Male

**Target number of participants**

75

**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

**Sponsor details**

Newcastle Road

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consumeraffairs.west@hse.ie

**Sponsor type**

University/education

**Website**

<https://www.universityofgalway.ie>

**ROR**

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

**Funder(s)****Funder type**

Other

**Funder Name**

Investigator initiated and funded

**Results and Publications****Publication and dissemination plan**

Planned publication in a peer-reviewed journal

**Intention to publish date**

01/06/2025

**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](mailto:eoin645@outlook.com)

**IPD sharing plan summary**

Available on request