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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
28/04/2025	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
29/04/2025	Completed	Results
Last Edited	Condition category	Individual participant data
29/04/2025	Surgery	[X] 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
Patrick O'Malley, paddyomalley@hotmail.com
Dr Patrick Neligan, pjneligan@yahoo.com

### Contact information

#### Type(s)

Public, Scientific

#### Contact name

Dr Eoin Coughlan

#### **ORCID ID**

https://orcid.org/0009-0007-3482-0698

#### Contact details

Apt 31, Merton Hall
Milltown Avenue, Mount St Annes
Dublin 6
Ireland
D06 DX00
+353 851646017
eoin645@outlook.com

#### Type(s)

Principal investigator

#### Contact name

Mr Patrick O'Malley

#### Contact details

Galway University Hospital Galway Ireland H91 YR71 +353 874194709 paddyomalley@hotmail.com

#### Type(s)

Principal investigator

#### Contact name

Dr Patrick Neligan

#### Contact details

Galway University Hospital Galway Ireland H91 YR71

#### Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### ClinicalTrials.gov (NCT)

Nil known

#### 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

#### **Study outputs**

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

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