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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

Registration date
29/04/2025

Overall study status
Completed

Last Edited
29/04/2025

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[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
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Public, Scientific

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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
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Sponsor information

Organisation
Ollscoil na Gaillimhe – University of Galway

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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

IPD sharing plan summary
Available on request