Clinical trial results:
Comparison of continuous Lumbar Epidural (LEP) and Transversus Abdominis Plane (TAP) Blockade in the management of postoperative pain post abdominal surgery.

Summary

EudraCT number	2006-004317-18
Trial protocol	IE
Global end of trial date	28 May 2010

Results information

Result version number	v1 (current)
This version publication date	22 October 2022
First version publication date	22 October 2022
Summary attachment (see zip file)	Prostate (Finnerty et al.doc) Morphine consumption (Postoperative Morphine Consumption.jpg) Pain scores up to 24hr (VAS < 24hr.jpg) Pain scores 24hr to 72hr. (VAS 24-72 hr.jpg) Intraoperative hemodynamics (Intraoperative hemodynamics.jpg) Postoperative hemodynamics (Postop hemodynamics.jpg) Sensory block level (Sensory Block.jpg)

Trial information

Trial identification

Sponsor protocol code	TAP4

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Dept Anaesthesia, UCHG
Sponsor organisation address	Newcastle Rd, Galway, Ireland,
Public contact	Dr Olivia Finnerty, Dept Anaesthesia, University College Hospital Galway, +353 91544074, olivia.finnerty@hse.ie
Scientific contact	Dr Olivia Finnerty, Dept Anaesthesia, University College Hospital Galway, +353 91544074, olivia.finnerty@gmail.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No

Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	30 April 2012
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 May 2010
Global end of trial reached?	Yes
Global end of trial date	28 May 2010
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

In this study, we aim to compare the analgesic efficacy of TAP block to epidural blockade in the first 72 postoperative hours by monitoring pain score, in patients undergoing retropubic prostatectomy, in a randomized controlled single blind clinical trial.

Protection of trial subjects:

Each patient was reminded that they were free to discontinue participation in the trial at any time. The option of further analgesia was available to all patients at all times.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 September 2008
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Ireland: 72
Worldwide total number of subjects	72
EEA total number of subjects	72

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0

Adolescents (12-17 years)	0
Adults (18-64 years)	57
From 65 to 84 years	15
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Each patient was invited to enroll in the study when they were booked for open retropubic prostate surgery.

Pre-assignment

Screening details:

ASA I-III men, between 18 and 80 years, presenting for elective retropubic prostatectomy, via an infra-umbilical incision in a prospective randomized, single blinded, controlled, clinical trial.
Exclusion criteria included relevant drug allergy, a contraindication to neuraxial analgesia, renal dysfunction or sepsis.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Epidural

Arm description:

This group had epidural analgesia

Arm type	Active comparator
Investigational medicinal product name	Levobupivacaine
Investigational medicinal product code	PL00037/0300
Other name	CHirocaine
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Perineural use

Dosage and administration details:

Levobupivacaine 0.25% was given into the epidural space and a continuous infusion started for 24hrs.

Arm title	TAP block

Arm description:

This group received a TAP block intraoperatively.

Arm type	Active comparator
Investigational medicinal product name	Levobupivacaine
Investigational medicinal product code	PL00037/0300
Other name	CHirocaine
Pharmaceutical forms	Solution for injection
Routes of administration	Not mentioned

Dosage and administration details:

0.25% Levobupivacaine was used to perform the TAP block. Each patient received 30ml each side, i.e. 60ml in total.

Number of subjects in period 1	Epidural	TAP block
Started	41	31
Completed	29	31
Not completed	12	0
Protocol deviation	12	-

Baseline characteristics

Reporting groups	
Reporting group title	Epidural
Reporting group description:	
This group had epidural analgesia	
Reporting group title	TAP block
Reporting group description:	
This group received a TAP block intraoperatively.	

Reporting group values	Epidural	TAP block	Total
Number of subjects	41	31	72
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	34	26	60
From 65-84 years	7	5	12
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	57.7	59.3	
standard deviation	± 7.9	± 7.2	-
Gender categorical Units: Subjects			
Male	41	31	72

End points

End points reporting groups

Reporting group title	Epidural
Reporting group description:	
This group had epidural analgesia	
Reporting group title	TAP block
Reporting group description:	
This group received a TAP block intraoperatively.	

Primary: End point

End point title	End point
End point description:	
End point type	Primary
End point timeframe:	
The primary outcome measure in this study was pain severity at rest and on movement over the first 24 postoperative hours.	

End point values	Epidural	TAP block		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29	31		
Units: 0 to 10				
arithmetic mean (standard deviation)	0.97 (± 0.64)	2.16 (± 1.01)		

Attachments (see zip file)	Pain Scores at Rest and Movement.jpg Postoperative Morphine Consumption.jpg

Statistical analyses

Statistical analysis title	Satistical analysis
Statistical analysis description:	
Statistical analyses were performed using a standard statistical program (Sigmastat 3.5, Systat Software, San Jose, CA, USA). Demographic data were analyzed using Student's t or Fisher's exact tests as appropriate. The data were tested for normality using the Kolmogorov-Smirnov normality test. Repeated measurements (e.g. pain scores, heart rate, blood pressure) were analyzed by repeated measures ANOVA where normally distributed, with paired comparisons performed using the t test.	
Comparison groups	Epidural v TAP block

Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	≤ 0.01 [1]
Method	t-test, 2-sided

Notes:

[1] - See figure 'Pain scores in the first 24hours' for interval p values.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were monitored from the start of anaesthesia until after the last data collection time point at 72hours.

Assessment type	Non-systematic

Dictionary used

Dictionary name	None
Dictionary version	0

Reporting groups

Reporting group title	Adverse Events TAP group
Reporting group description: -	
Reporting group title	Adverse events Epidural group

Reporting group description: -

Serious adverse events	Adverse Events TAP group	Adverse events Epidural group	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 31 (3.23%)	0 / 29 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Cardiac disorders			
Non ST elevated MI			
subjects affected / exposed	1 / 31 (3.23%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Respiratory arrest	Additional description: One patient developed respiratory arrest while on his PCA morphine. This lead to a NSTEMI and TIA. He was resusitated with naloxone and moved to the ICU. He made a fully recovery. He failed to disclose known coronary artery disease preoperatively		
subjects affected / exposed	1 / 31 (3.23%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Adverse Events TAP group	Adverse events Epidural group	
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 31 (0.00%)	1 / 29 (3.45%)	
Nervous system disorders			
Epidural puncture	Additional description: One patient had a dural puncture during epidural insertion. The epidural was successfully re sited and used successfully. The patient did not develop a headache.		
subjects affected / exposed	0 / 31 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
06 July 2009	The study was paused for 3 months due to serious illness and death of one of the core investigators	28 September 2009
01 March 2010	One of the core investigators was travelling to New Zealand and travel home was delayed by three weeks due the eruption of the Icelandic Volcano that caused airline traffic chaos.	12 April 2010

Notes:

Limitations and caveats

None reported