Evaluation of the Transversus abdominis plane block (TAP-block) in preventing painful urine bladder spam in patients undergoing Robot Assisted Laparoscopic Radical Prostatectomy under general anesthesia, a prospective randomized controlled trial

Published: 15-10-2007
Last updated: 09-05-2024

To evaluate the value of a TAP-block for the reduction of postoperative bladder spasm after RALP for prostate cancer

Ethical review	Approved WMO
Status	Pending
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Interventional

Summary

ID

NL-OMON31036

Source
ToetsingOnline

Brief title
TAP in RALP

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
bladder spasm

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bladder spasm, RALP, TAP-block

Outcome measures

Primary outcome

The incidence rate of postoperative bladder spasm at 1 hour after arrival at the recovery room , 4 hours postoperatively and on the morning of the first postoperative day.

Secondary outcome

Pain by NRS (0 - 10) , done one hour after arrival at the recovery room , 4 hours postoperatively and on morning of the first postoperative day.

Postoperative nausea and vomiting during the period end of the surgical procedure till 12:00 am of the first postoperative day.

The cumulative dose of oxybutinine and butylscopolamine and morfine given between the arrival at the recovery room and 12 am on the morning of the first postoperative day.

Study description

Background summary

The incidence rate of bladder spasm after robot assisted laparoscopic radical prostatectomy (RALP) under general anesthesia is high and may be 64% . The

incidence rate of bladder spasm decreases to 33% without the use of any anti-cholinergic agent or any spasmolytic agent in patients receiving a transversus abdominis plane-block (TAP-block) just after de induction of anesthesia but before the start of surgery.

Study objective

To evaluate the value of a TAP-block for the reduction of postoperative bladder spasm after RALP for prostate cancer

Study design

single blinded, placebo-controlled.

Intervention

A bilateral TAP-block is performed in patients undergoing a RALP for prostate cancer, randomized for TAP-block.

Study burden and risks

advantage: more comfort during the postoperative period than after a standard procedure.
disadvantage: a bilateral blood extravasation in the skin overlying Petit's triangle such as may occur after a normal venepunction.
As is the case in any regional anesthesia technique, the local anesthetic agent may be injected intravenously when the instructions for proper performance of a TAP block are neglected with the ultimate consequences of an local anesthetic intoxication.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
1066 CX Amsterdam
NL
Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
1066 CX Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Men with prostate cancer scheduled for robot assisted laparoscopic radical prostatectomy (RALP)

Exclusion criteria

Mental disorders.
Inability to communicate in Dutch or English language
Re-intervention procedures after (RALP)
Conversion form RALP to an open procedure
Allergy for amide type local anesthetic agents
Allergy for oxybutinine, or butylscopolamine
Allergy to acetaminophen
Allergy to diclofenac.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2008
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	macaine 0.5%
Generic name:	bupivacaine-HCl 0.5%
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	15-10-2007
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2007-004799-38-NL
CCMO	NL19509.031.07