

Effects of anaesthetic technique on inflammatory stress response following laparoscopic hysterectomy in endometrial cancer patients: general anaesthesia combined with Transverse Abdominal Plane blockade (TAP) versus general anaesthesia and thoracic epidural analgesia (TEA).

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Determine which anaesthetic technique (general anaesthesia in combination with TAP blockade versus general anaesthesia in combination with thoracic epidural analgesia) offers the most benefits, with respect to attenuation of the surgical inflammatory...

Ethical review	Not approved
Status	Will not start
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON43516

Source

ToetsingOnline

Brief title

TAP versus TEA

Condition

- Reproductive neoplasms female malignant and unspecified
- Uterine, pelvic and broad ligament disorders

Synonym

endometrium cancer, Endometrium carcinoma

Research involving

Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: CGOA voor betaling bepalingen

Intervention

Keyword: anesthesia technique, Endometriumcarcinoma, inflammatory stress response

Outcome measures**Primary outcome**

Levels of cytokines (pro- and anti-inflammatory), procalcitonin, NLR and

C-reactive protein

Secondary outcome

1) Intensity of wound pain at rest and during movement by Numeric Rating Scale

2) The number of milligrams of opioids and NSAID consumed by the patient.

3) Health-related quality of life (HR-QOL) will be determined by EuroQol instrument (EQ-5D).

4) Side effects such arrhythmias, hemodynamic changes and post epidural headache will be registered and recorded as absent or present.

5) Length of hospital stay will be calculated and expressed in number of days.

Study description**Background summary**

Evidence is growing that inflammation plays an important role in cancer

evolution. There is also growing appreciation that surgery, and the accompanying inflammatory stress response, might induce immunosuppression through which cancer cells are promoted to grow and metastasize. Although opioids are traditionally used to attenuate the surgical inflammatory stress response, there is also evidence that opioids might paradoxically induce further immunosuppression and thereby promote cancer growth. Neuraxial blockade has been shown to attenuate the stress response, thereby preserving immunity. Adjuvant loco-regional techniques, like for instance Transverse Abdominal Plane (TAP) blockade, are increasingly used to decrease the need for opioids and to preserve immunity as much as possible. However, in case of laparoscopic hysterectomy, there is lack of evidence indicating which adjuvant type of analgesia most effectively attenuates pain and the stress response. The aim of this study is to determine which anaesthetic technique (general anaesthesia in combination with TAP blockade versus general anaesthesia in combination with thoracic epidural analgesia) offers the most benefits, with respect to attenuation of the surgical inflammatory stress response

Study objective

Determine which anaesthetic technique (general anaesthesia in combination with TAP blockade versus general anaesthesia in combination with thoracic epidural analgesia) offers the most benefits, with respect to attenuation of the surgical inflammatory stress response, pain intensity and Health-related quality of life (HR-QOL).

Study design

Prospective longitudinal study of six month for changes in cytokine concentrations before and after surgery.

Study burden and risks

Not applicable

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- * Patients scheduled for elective laparoscopic hysterectomy, laparoscopic staging procedures, laparoscopic radical hysterectomy.
- * Adult patients (older than 18 years of age)
- * Written informed consent
- * Understanding of Dutch or English language

Exclusion criteria

- * Non-elective surgery
- * Any contraindication to neuraxial blockade (including coagulopathy, abnormal anatomy)
- * Allergy to amide-linked local anaesthetics, especially bupivacaine
- * Known psychiatric disorder
- * Chronic pain patients or patients already using morphine pre-operatively

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Not approved	
Date:	07-03-2016
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
CCMO	NL55841.031.16