Afweer beschermende werking van narcose middelen tijdens een operatie voor darmkanker

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We hypothesize that an immune protective anesthesia strategy for cancer patients preserves immune response during endoscopic colon surgery

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23133

Bron
Nationaal Trial Register

Verkorte titel
DEFENSE-II

Aandoening

Colon Cancer, Anesthesiology, Immune response

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: fund=initiator=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter is the immunological response between conventional anesthesia

and immune protective anesthesia after 24 hours.

Toelichting onderzoek

Achtergrond van het onderzoek

Surgical resection for cancer is still the mainstay of treatment. Although multimodal treatment of cancer patients has improved dramatically, there is increasing evidence that the method of anesthesia might improve cancer free survival. Anesthesia is known to influence the immune response, mostly in a negative way by depressing natural killer (NK) cell activity and T-cell lymphocytes. However, during surgical resection of a solid tumor, a well functioning immune response is pivotal to eliminate micro-metastases. Anesthesia during cancer surgery should be focused on immune protection without compromising patient's safety or comfort in the perioperative phase. We hypothesize that an immune protective anesthesia strategy for cancer patients preserves immune response during endoscopic colon surgery.

Doel van het onderzoek

We hypothesize that an immune protective anesthesia strategy for cancer patients preserves immune response during endoscopic colon surgery

Onderzoeksopzet

Bloodsamples are taken on:

T0=prior to study

T1=24hrs after surgery

T2=48hrs after surgery

Onderzoeksproduct en/of interventie

1. Conventional anesthesia:

- Preoperative Paracetamol

- Intravenous analgesia with opioids and postoperative pain management with Dipidolor or morphine according to local protocols.

- Anesthesia only with Sevoflurane; dosage according to the bispectral index scale (BIS) with target values between 40 and 60.

- Ketamine, Clonidine and Dexamethason according to the judgment of the anesthesiologist.

- No Dexmedetomidine, epidurale analgesia, continueous lidocaine or COX-2 inhibitor.

2. Immune protective regime:

- Single dose of preoperative Paracetamol and Midazolam (dosage according to anesthesiologist)

- Analgesia perioperative: epidural (only with local anesthetic), Paracetamol, Dexmedetomidine (between 0.2 and 1.0 ug/kg/hr without any bolus) starting before epidural

- Analgesia postoperative: epidurale analgesia according to local protocols (only with local anesthetic) and Paracetamol

- Anesthesia only with Propofol; dosage according to the bispectral index scale (BIS) with target values between 40 and 60.

- Without peri- or postoperative use of opiates, Ketamine, Clonidine or Dexamethason

- Hypotension should preferably be treated with phenylephrine

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- All patients approved by the anesthesiologist for elective endoscopic colon surgery for cancer.

- > 18 year with written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- neoadjuvant chemo and/or radiotherapy

- Perioperatieve conversion to an open surgical approach

- Insufficient pain relief in the intervention group (Visual Analogue Scale (VAS) ≥ 4)

- Absolute contra-indications for the use of a any of the listed medications or procedures (epidural) in the intervention group

- Synchronous metastasis (stage IV/ M1 patients)

- Patients who are mentally disabled or incapable to give informed consent

- Patients on chronic opioid therapy

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	06-08-2018
Aantal proefpersonen:	366
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-08-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46294
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7216
NTR-old	NTR7415
CCMO	NL58206.056.17
OMON	NL-OMON46294

Resultaten