# Afweer beschermende werking van narcose middelen tijdens een operatie voor darmkanker

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON23133

**Source**
Nationaal Trial Register

**Brief title**
DEFENSE-II

**Health condition**

Colon Cancer, Anesthesiology, Immune response

### Sponsors and support

**Primary sponsor:** University Medical Center Groningen
**Source(s) of monetary or material Support:** fund=initiator=sponsor

### Intervention

### Outcome measures

**Primary outcome**

The main study parameter is the immunological response between conventional anesthesia and immune protective anesthesia after 24 hours.

### Secondary outcome

Is there a difference between patients with conventional and immune protective anesthesia regarding:

1. Immunological response between two different anesthesia strategies after 48 hours postoperative

2. Minor and major postoperative complications according to the Clavien Dindo classification

3. Postoperative VAS (Visual Analogue Scale) score

4. Hospital stay

5. Anesthetic variables

## Study description

### Background summary

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.

### Study objective

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

### Study design

Bloodsamples are taken on:

T0=prior to study

T1=24hrs after surgery

T2=48hrs after surgery

**Intervention**

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

# Contacts

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# Eligibility criteria

## Inclusion criteria

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

- > 18 year with written informed consent

## Exclusion criteria

- 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

# Study design

## Design

Study type: Interventional

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| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 06-08-2018 |
| Enrollment: | 366 |
| Type: | Anticipated |

## Ethics review

Positive opinion

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|---|---|
| Date: | 01-08-2018 |
| Application type: | First submission |

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 46294
Bron: ToetsingOnline
Titel:

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

No registrations found.

### In other registers

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

## Study results