

Stimuleren van het onwillekeurige zenuwstelsel met perioperatieve voeding bij patiënten die een darmoperatie ondergaan.

Gepubliceerd: 07-07-2014 Laatste bijgewerkt: 19-03-2025

Giving perioperative lipid-enriched nutrition in colorectal surgery stimulates the autonomic nervous system leading to an anti-inflammatory effect. This will lead to a decrease in postoperative ileus and anastomotic leakage.

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

Samenvatting

ID

NL-OMON20551

Bron

NTR

Verkorte titel

SANICS II

Aandoening

Postoperative ileus, anastomotic leakage, colorectal surgery, enteral nutrition, intestinal damage, inflammation

Ondersteuning

Primaire sponsor: Catharina Hospital Eindhoven

Overige ondersteuning: ZonMW

Danone/Nutricia

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Postoperative ileus

Toelichting onderzoek

Achtergrond van het onderzoek

Postoperative ileus (POI) and anastomotic leakage (AL) are important complications following colorectal surgery associated with short-term morbidity and mortality. Previous experimental and preclinical studies have shown that a short intervention with enriched enteral nutrition dampens inflammation via stimulation of the autonomic nervous system and thereby reduces POI. Furthermore, early administration of enteral nutrition after surgery reduced AL. This study investigates the effect of nutritional stimulation of the autonomic nervous system just before, during and after surgery on inflammation, POI and AL.

This multicentre, prospective, double blind, randomised controlled trial will include 280 patients undergoing colorectal surgery. All patients receive a selfmigrating nasojejunal tube that will be connected to a custom-made blinded tubing. Subsequently, patients are allocated to either the intervention group, receiving perioperative nutrition or to the control group, receiving no nutrition. Primary endpoints are POI and AL. Secondary endpoints are local and systemic inflammation, (aspiration) pneumonia, surgical complications classified according to Clavien-Dindo, quality of life, gut barrier integrity and length of functional recovery. Furthermore, a cost-effectiveness analysis will be performed.

Activation of the autonomic nervous system via perioperative enteral feeding is expected to dampen the local and systemic inflammatory response. Consequently, POI will be reduced as well as AL. The present study is the first to investigate the effects of enriched nutrition given shortly before, during and after surgery in a clinical setting.

Doel van het onderzoek

Giving perioperative lipid-enriched nutrition in colorectal surgery stimulates the autonomic nervous system leading to an anti-inflammatory effect. This will lead to a decrease in postoperative ileus and anastomotic leakage.

Onderzoeksopzet

1. Postoperative ileus: within 1 week after surgery by daily control of clinical parameters, and rate of gastric emptying at postoperative day 2.
2. Anastomotic leakage: within 6 weeks after surgery by clinical/radiological signs or confirmed by reoperation.
3. Inflammatory response: bloodsamples: preoperatively, 4-24-48hours postoperatively, tissue sample and peritoneal lavage sample during surgery.
4. Quality of life: preoperatively, 3 months, 6 months

Onderzoeksproduct en/of interventie

All patients receive a selfmigrating nasojejunal tube. Via a custom-made tubing system blinding will be ensured.

Intervention group: patients will receive enriched enteral nutrition from 3 hours prior to surgery, until 6 hours after surgery.

Control group: patients will not receive nutrition, but via the special tubing, the nutrition will be collected in a bedside-container instead.

Contactpersonen

Publiek

Department of Surgery, Catharina Hospital, P.O. Box 1350, 5623EJ
E.G. Peters
Eindhoven
The Netherlands
+31-40-2396350

Wetenschappelijk

Department of Surgery, Catharina Hospital, P.O. Box 1350, 5623EJ
E.G. Peters
Eindhoven
The Netherlands
+31-40-2396350

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Elective segmental colorectal resection with primary anastomosis
2. Written informed consent
3. Age >18 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous gastric or oesophageal resection
2. Pre-existent or creation of ileostoma
3. Steroid use
4. Use of medication that disrupts acetylcholine metabolism (SSRI's or anticonvulsants)
5. Peritoneal metastases

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	10-07-2014
Aantal proefpersonen:	280

Type: Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 07-07-2014

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41286

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4494
NTR-old	NTR4670
CCMO	NL45640.060.13
OMON	NL-OMON41286

Resultaten