Stimuleren van het onwillekeurige zenuwstelsel bij patienten die een darmoperatie ondergaan.

No registrations found.

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

Summary

ID

NL-OMON26402

Source
Nationaal Trial Register

Brief title
SANICS

Health condition

postoperative ileus, postoperatieve ileus
inflammation, ontsteking
colorectal surgery, colorectale chirurgie
intestinal damage, darmschade
enteral nutrition, enterale voeding

Sponsors and support

Primary sponsor: Orbis Medical Centre
Catharina hospital Eindhoven
Source(s) of monetary or material Support: initiator = sponsor

Intervention

Outcome measures

Primary outcome

1. Lenght of stay;

2. Time to first flatus/ defaecation;

3. Infectious complications.

Secondary outcome

1. Effect on inflammation (cytokines);

2. Effect on intestinal damage;

3. Effect on gastrointestinal passage (ultrasound);

4. Morbidity and mortality.

Study description

Background summary

We hypothesized that stimulation of the autonomic nervos system via de vagal nerve reduces the postoperative inflammatory response after colorectal surgery. In this way, complications such as postoperative ileus will be reduced and recovery after surgery is enhanced. Experimental studies already showed that vagal nerve stimulation reduces postoperative ileus and decreases the inflammatory response following hemorrhagic shock, endotoxemia and ischemia/ reperfusion. Stimulation of the autonomic nervous system releases acetylcholine that binds to nictotinic receptors located on inflammatory cells. Hereby, production of inflammatory mediators is directly inhibited. It is thought that the chewing of gum activates the autonomic nervous system vai de vagus nerve.
Patients undergoing colorectal surgery will be included in this study and divided into two groups. Group one will receive chewing gum three hours preoperatively until time of surgery. Three hours postoperatively chewing gum will be distributed again to the patients until the start of enteral nutrition. All patients in group two, the placebo controlled group, will receive a dermal patch three hours preoperatively. This dermal patch will be removed until the first moment of oral nutrition is achieved. Preoperatively the vagal activity of all patients will be measured by variation of the heartbeat via blood pressure measurements, electrocardiographs and impedance cardiographs.

Primary study parameters/outcome of the study: Length of hospital stay, occurrence of postoperative ileus.

Secundary study parameters/outcome of the study: Inflammatory cytokines and acute phase proteins (TNF-alpha, IL-6, CRP). Mediators of the inflammatory response in bowel tissue. Expression of nitric oxide synthases and their precursor arginine in plasma. The effect on tissue damage in the bowel, specified by measuring tissue damage markers in plasma and specifying bowel damage in the removed specimens and 24h-urine. Morbidity and mortality.

Study objective

Chewing gum before and directly after colorectal surgery stimulates the autonomic nervous system leading to an antiinflammatory effect.

Study design

Blood samples: 2u, 4u, 6u, 12u, 24u, 48u;

Ultrasound: Day 2.

Intervention

Intervention group: Patiënts will receive chewing gum pre-operative from the moment they are sober untill the operation. They will start again four hours after the operation untill normal food is again taken.

Control groups: These patiënts will receive a plaster as a placebo.

Contacts

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Eligibility criteria

Inclusion criteria

1. Resectable colorectal carcinoma;

2. Age >18 years.

Exclusion criteria

1. Previous esofageal/ stomach surgery;

2. Neurological disorders influencing acetylcholine metabolism;

3. Use of SSRI;

4. Depression;

5. Inflammatory bowel disease;

6. Medication influencing gut motility;

7. Allergy for mint;

8. Metastatic disease;

9. Stoma.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-10-2008
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-04-2011
Application type:	First submission

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
NTR-new	NL2729
NTR-old	NTR2867
Other	METC : 08-T-70
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A