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

Gepubliceerd: 26-04-2011 Laatst bijgewerkt: 18-08-2022

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

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

Samenvatting

ID

NL-OMON26402

Bron
Nationaal Trial Register

Verkorte titel
SANICS

Aandoening

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

Ondersteuning

Primaire sponsor: Orbis Medical Centre
Catharina hospital Eindhoven
Overige ondersteuning: initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Lenght of stay;
2. Time to first flatus/ defaecation;
3. Infectious complications.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

Chewing gum before and directly after colorectal surgery stimulates the autonomic nervous

system leading to an antiinflammatory effect.

Onderzoeksopzet

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

Ultrasound: Day 2.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Resectable colorectal carcinoma;

2. Age >18 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	03-10-2008
Aantal proefpersonen:	120

Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-04-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2729
NTR-old	NTR2867
Ander register	METC : 08-T-70
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A