Early Total Parenteral versus Enteral Nutrition to Reduce Postoperative Ileus after Major Rectal Surgery.

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1- Our hypothesis is that the incidence of POI will decrease more in Group 1 (receiving enteral nutrition) than in group 2 (receiving parenteral nutrition). 2- Group 1 (receiving enteral nutrition) will have more days of vomiting in comparison...

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

Samenvatting

ID

NL-OMON25240

Bron
NTR

Verkorte titel
N/A

Aandoening

Nutrition, Rectal Surgery, Ileus, Infection, Length of hospital stay, Amino acids, Glucose, Immune function

Voeding, Rectum chirurgie, Ileus, Infectie, Duur van opname, Aminozuren, Glucose, Immuunsysteem

Ondersteuning

Primaire sponsor: Nutritia
Overige ondersteuning: Nutritia

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Postoperative Ileus

Toelichting onderzoek

Achtergrond van het onderzoek

The main objective of this clinical study is to reduce postoperative ileus by early enteral nutrition as compared to early parenteral strategies in patients undergoing rectal surgery. Comparing different early strategies of artificial nutrition in combination with standard care will generate valuable information about the incidence of ileus, infectious complications and hospital length of stay in this population.

Doel van het onderzoek

1- Our hypothesis is that the incidence of POI will decrease more in Group 1 (receiving enteral nutrition) than in group 2 (receiving parenteral nutrition).

2- Group 1 (receiving enteral nutrition) will have more days of vomiting in comparison to group 2 (receiving parenteral nutrition).

3- Early enteral nutrition (group 1) will have a shorter hospital length of stay in comparison to group 2.

4- Patients from group 1 (receiving enteral nutrition) will return to a normal diet sooner as compared with other group 2 (receiving parenteral nutrition).

Onderzoeksopzet

V-1= Pre-operatively (one day before surgery)

V1= Postoperatively Day 1

V2= Postoperatively Day 5

V3= Day of discharge

Onderzoeksproduct en/of interventie

1- Enteral nutrition starting 8 hours postoperatively

2- Parenteral nutrition starting 8 hours postoperatively

Contactpersonen

Publiek

Catharina-ziekenhuis
P.G. Boelens
Michelangelolaan 2
Eindhoven 5623 EJ
The Netherlands
+31 (0)40 2399111

Wetenschappelijk

Catharina-ziekenhuis
P.G. Boelens
Michelangelolaan 2
Eindhoven 5623 EJ
The Netherlands
+31 (0)40 2399111

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients who will undergo elective major rectal surgery such as low anterior resection or abdominal perineal resection with or without intra-operative radiotherapy (IORT) for primary or recurrent disease.

2. Fit for elective surgery as defined by ASA score 1 to 3. (Whereby ASA 1 corresponds to a healthy patient. ASA 2 corresponds to a patient with mild, controlled, functionally non-limiting systemic disease and ASA 3 corresponds to a patient with severe or poorly controlled systemic disease that is functionally limiting).

3. Having obtained his/her informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients undergoing an emergency rectal operation.

2. Patients undergoing synchronous partial liver or pulmonary resection.

3. Esophageal varices or known with gastric or esophageal bleeding.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	05-01-2009
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	05-11-2008
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	NL678
NTR-old	NTR1523
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A