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

No registrations found.

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

Summary

ID

NL-OMON25240

Source
Nationaal Trial Register

Brief title
N/A

Health condition

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

Sponsors and support

Primary sponsor: Nutritia
Source(s) of monetary or material Support: Nutritia

Intervention

Outcome measures

Primary outcome

- Postoperative Ileus

Secondary outcome

- Nutritional status

- Complications (infection, diarrhea, vomiting, high gastric residuals)

- Length of hospital stay

- Amino acids profile

- Glucose metabolism

- Routine blood measurements

- Acute Phase Response

Study description

Background summary

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.

Study objective

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).

Study design

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

V1= Postoperatively Day 1

V2= Postoperatively Day 5

V3= Day of discharge

Intervention

1- Enteral nutrition starting 8 hours postoperatively

2- Parenteral nutrition starting 8 hours postoperatively

Contacts

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

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-01-2009
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-11-2008

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	NL678
NTR-old	NTR1523
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A