PRE-OCC study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26935

Source
Nationaal Trial Register

Brief title
PRE-OCC

Health condition

Obstructive colon cancer

Sponsors and support

Primary sponsor: Wetenschapsacademie Amphia
Source(s) of monetary or material Support: Amphia wetenschapsacademie

Intervention

Outcome measures

Primary outcome

Complication-free survival (CFS) at 90 days after hospitalization. Complication is defined here as mortality and/or development of a major complication (Clavien-Dindo classification >2).

Secondary outcome

Complications, creation of primary anastomosis, stoma creation, radical tumour resection, operative blood loss, operation time, total hospital stay (in total, after resection or

reoperation), oncological resection. With a follow up of 1 year.

Study description

Background summary

Prospective registration of the implementation of the pre-optimization protocol in patients with (acute) malignant obstruction of the colon, without suspicion of perforation (tumour perforation or blow out). Pre-optimization consist of optimization of physical health, and nutritional health before definite tumour resection.

Study objective

Implementation of the preoptimisation protocol in patients presenting with obstructive colon cancer will reduce the mortality and morbidity postoperatively.

Study design

Baseline, 90 days after hospitalization, follow-up (following the colon cancer protocol at 3/6/9/12 months post-operatively).

Intervention

Prosective registration of the implementation of the pre-optimization protocol in patients with obstructive colon cancer.

Contacts

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Eligibility criteria

Inclusion criteria

- Patients 18 years or older.
- Patients presenting with symptoms of bowel obstruction caused by (high suspicion or histologically proven) colonic cancer.
- Patients presenting with (partial) obstruction (abdominal pain, nausea, vomiting, diarrhoea) confirmed by the presence of a dilated colon or ileum with a computed tomography (CT-scan).

Exclusion criteria

- Obstruction of the colon pathologically caused by benign disease.
- Obstruction of the colon caused by an extra-colonic malignancy.
- Suspicion of emergency complications caused by peritonitis due to perforation (tumour or blow out) or sepsis.
- Rectal cancer

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2020
Enrollment:	110
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N/A

Ethics review

Positive opinion
Date: 06-01-2020
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	NL8266
Other	Medical research Ethics Committees United (MEC-U) : W19.249

Study results

Summary results
N/A