Implementation of optimized and standardized surgical technique for right-sided colon cancer: a prospective interventional sequential cohort study with a transition period

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON53738

Source
ToetsingOnline

Brief title
Right Study (part 2)

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal therapeutic procedures

Synonym
Right-sided colon cancer; right-sided colon tumors

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W,Johnson & Johnson Pharmaceutical,Medtronic

Intervention

Keyword: Laparoscopic right hemicolectomy, Right-sided colon cancer, Standardize, Surgical variations

Outcome measures

Primary outcome

The primary endpoint is the 90-day morbidity with Clavien-Dindo classification.

Secondary outcome

• Intraoperative complications (i.e. vascular injury, injury to other organs);

• 90-day mortality;

• Conversion;

• Operative time;

• Blood loss;

• Validated assessment of plane of dissection;

• Validated assessment of level of vascular ligation;

• Grading of the resection specimen according to Benz et al. [17];

• Total lymph node count;

• Number of resected positive lymph nodes;

• Resection margins;

• Completeness of mesocolic excision based on postoperative CT imaging;

• Locoregional recurrence;

• Distant metastasis;

• 3-year disease free survival (DFS);

• 5-year overall survival (OS);

• Long-term morbidity: incisional hernia, adhesion related small bowel

obstruction, readmissions, reinterventions, anastomotic leakage.

Study description

Background summary

Surgical procedures for gastrointestinal oncology intervention are inevitably variable amongst surgeons and centers. Although this variation is acceptable to a certain degree, a substantial proportion of this variability has a potential relevance for both short term clinical outcomes and long term oncological survival. For patients with right-sided colon cancer, a laparoscopic right hemicolectomy (LRHC) is the surgical procedure of choice to remove the cancer and locoregional lymph nodes. This surgical technique has evolved during the last decade with the introduction of the intracorporeal anastomosis, the Pfannenstiel extraction and the complete mesocolic excision (CME). The latter is a dissection technique in embryological planes with a central vascular ligation of the segmental branches at its origin, resulting in an optimal lymphadenectomy. Given the insights from recent studies showing a positive association between the quality of surgery and relevant clinical outcomes, there is a great need to reduce the interinstitutional and intersurgeon variability and to implement an optimized and standardized surgical technique for right-sided colon cancer in the Netherlands to improve short- and long-term clinical and oncological outcomes. Currently, within the LRHC, there is variation in the way the procedure is performed and the majority of surgeons in the Netherlands have not implemented one or more elements of the right hemicolectomy as is recommended by the recent Dutch and international guidelines. This implicates potential to improve clinical outcomes by implementing all recommended steps of LRHC. This kind of implementation needs a consensus of the national society of colorectal surgeons for the key elements of the procedure to be incorporated in an uniform procedure to be trained, implemented and to allow formative quality assessment. Detailed objective assessment of the LRHC is currently not performed in clinical practice nor in surgical training. Quality assessment of LRHC has great potential to improve surgical training and furthermore, implementation of a standardized technique will ultimately lead to better quality of care for patients suffering from right-sided colon cancer.

Study objective

The main objective of this study is to improve surgical and oncological outcomes for patients with right-sided colon cancer by conducting a prospective sequential interventional cohort study that aims to evaluate national implementation of the LRHC as a standardized surgical technique (determined in a completed Delphi study, based on best evidence and existing guidelines) into current practice in a nationwide multicenter setting.

Study design

A prospective interventional sequential cohort study with a transition period.

Intervention

Implementation of the standardized right hemicolectomy with proctoring during a subsequent period with prospective inclusion of consecutive patients and the collection of surgical videos in all participating hospitals. The standardized right hemicolectomy consists of preoperatively properly assessing the (vascular) anatomy on the CT scan, applying pneumoperitoneum of 8-12mmHg, performing a complete mesocolic excision (CME) with central vascular ligation (CVL) which has been described in detail within the Delphi study, performing an intracorporeal anastomosis and extracting the specimen through the Pfannenstiel incision using a wound protector.

Study burden and risks

The combination of moderate harm and a low probability results in a risk classification of negligible risk. The likelihood of complications is very low since the standardized technique does not differ significantly or very little for most surgeons, and this technique is implemented in a very safe manner (comprehensive training and proctoring). Additionally, it's worth noting that this technique is already described in the guidelines in this way.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Planned laparoscopic or robot-assisted (extended) right hemicolectomy for colon cancer of
the caecum, ascending colon, hepatic flexure or proximal transverse colon
2) Age above 18 years
3) Signed informed consent

Exclusion criteria

1) cT4b/multivisceral resection
2) cTNM stage 4 (M1)
3) ASA 4
4) Immune modulating medication
5) Prior midline or transverse laparotomy larger than 10 cm (not including Pfannenstiel and McBurney's incision)
6) Perforated disease/peritumoral abscess/fistula
7) Acute obstruction
8) Emergency surgery
9) Neuroendocrine neoplasm (NEN)
10) Other malignancies treated within 5 years from diagnosis of colon cancer, except for curatively treated prostate, breast, skin and cervical cancer

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-10-2022
Enrollment:	730
Type:	Actual

Ethics review

Approved WMO Date:	19-01-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-09-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-01-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT04889456
CCMO	NL81212.029.22