Safety and cost-effectiveness of selective histopathological examination of appendices and gallbladders

No registrations found.

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

Summary

ID

NL-OMON23801

Source
NTR

Brief title
FANCY

Health condition

Appendix, Appendectomy, Gallbladder, Cholecystectomy, Pathology, Histopathological examination, Selective, Routine.

Appendix, Appendectomie, Galblaas, Cholecystectomie, Pathologie, Histopathologisch onderzoek, Selectief, Routinematig.

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

1. Number of patients per 1000 examined appendices/gallbladders with a neoplasm requiring additional therapy benefitting the patient that would have been unnoticed in the policy of selective histopathological examination.

2. Costs of the policy with selective and with routine histopathological examination of the appendix/gallbladder.

Secondary outcome

1. Incidence of malignancies in resected appendices and gallbladders.

2. Incidence of unnoticed malignancies in resected appendices and gallbladders.

3. Incidence of malignancies in resected appendices and gallbladders that subsequently require more extensive resection or other additional treatment.

4. Clinical consequences of more extensive resection or other additional treatment in patients with a malignancy found at histopathological examination of the appendix or gall bladder.

a. Remaining tumour tissue and/or positive lymph nodes in re-resection specimen

b. Postoperative complications

These secondary outcomes will also be reported for other aberrant findings as parasite infections, endometriosis, granulomatosis and benign neoplasms.

Study description

Background summary

Traditionally, all surgically removed appendices and gallbladders are sent to the department of pathology for histopathological examination. This is most likely not necessary in appendices and gallbladders that are not suspicious for a tumour when inspected visually or by palpation. If not detected by visual inspection or palpation, the tumour is usually of early stage and already treated with the resection of the organ. A policy of selective histopathological examination based on the intraoperative findings of the surgeon can probably reduce the amount of appendices and gallbladders that have to be examined by the pathologist, without a risk of undertreatment, with less risk of overtreatment and huge savings annually. In the FANCY study, a nationwide prospective multicenter observational cohort study, all appendices and gallbladders will be evaluated for tumours by visual inspection and palpation by the operating surgeon. The operating surgeon will report the his or her findings and also write down whether he or she thinks there is an indication for

histopathological examination. Subsequently, all specimens are sent to the pathologist for histopathological examination. Therefore, no aberrant findings will be missed due to this study. The prospective cohort can be compared through modelling to a hypothetical situation where appendices and gallbladders are only examined by the pathologist on indication. The primary outcome is the number of patients per 1000 examined appendices/gallbladders with a neoplasm requiring additional therapy benefitting the patient that would have been unnoticed in the policy of selective histopathological examination.

Study objective

Traditionally, all surgically removed appendices and gallbladders are sent to the department of pathology for histopathological examination. This is most likely not necessary in appendices and gallbladders that are not suspicious for a malignancy when inspected visually or by palpation. If not detected by visual inspection or palpation, the tumour is usually of early stage and already treated with the resection of the organ. A policy of selective histopathological examination based on the intraoperative findings of the surgeon can probably reduce the amount of appendices and gallbladders that have to be examined by the pathologist, without a risk of undertreatment, with less risk of overtreatment and huge savings annually. The objective of the FANCY study is to investigate whether a selective policy of histopathological examination of appendices and gallbladders based on the intraoperative findings of the surgeon is safe and cost-effective.

Study design

Primary outcomes

1. Number of patients per 1000 examined appendices/gallbladders (2 weeks)

2. Cost-minimisation analysis (9 months)

Secondary outcomes

1. Number of patients per 1000 examined appendices/gallbladders (2 weeks)

2. Number of patients per 1000 examined appendices/gallbladders (2 weeks)

3. Number of patients per 1000 examined appendices/gallbladders (3 months)

4a. % of patients that underwent a more extensive resection (3 months)

4b. % of patients that underwent a more extensive resection and description of complications (3 months)

Intervention

All appendices and gallbladders will be evaluated for tumours by the operating surgeon by visual inspection and digital palpation of the specimen. The appendix will not be opened. Particularly the top of the appendix is of interest since it is the preferred location of neuroendocrine tumours. Possible fecoliths can be squeezed out of the lumen. The galbladder is opened in its length, without cutting the ductus cysticus, and is inspected and palpated. The surgeon will report his findings on a predefined scoring form: he or she will report all abnormalities and writes down whether he or she considers there is an indication for histopathological examination. Subsequently, all specimens will be sent for histopathological examination. Histopathological examination will be conducted according to local protocol. In case of a neoplasm of the appendix or gallbladder, the treatment strategy is discussed and decided by the local multidisciplinary team. If an additional more extensive resection is decided to be appropriate, the specimens of the re-resection will be evaluated for the presence of remaining tumour tissue and positive lymph nodes.

One or two residents per participating hospital will be responsible for the prospective data collection and for entering the pseudonymised data into an electronic case record form (CRF) build with Castor EDC, which is ISO 27001 and NEN 7510 certified. Patients will be identified on a daily basis; pre- and intraoperative data will be processed after surgery, and the postoperative outcomes when the pathology report is available (± 2 weeks after surgery). Pre- and postoperative data will be obtained from the electronic patient database (EPD) and pathology reports. Intraoperative data will be obtained from operative reports in the EPD and forms that will be filled in by the surgeon intraoperatively. In case a neoplasm is found during histopathological examination, additional data about the consequences of the diagnosis will be collected. All additional medical or surgical treatments, perioperative morbidity and hospital stay will be monitored.

Contacts

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Eligibility criteria

Inclusion criteria

Patients of all ages who are scheduled to undergo an appendectomy or cholecystectomy in the elective or non-elective setting.

Exclusion criteria

Appendix:

- Primary indication for surgery: strong suspicion or proven malignancy in the appendix.

- Appendix removed as part of more extensive surgery, a so-called incidental appendectomy.

- Patients included in the ACCURE trial.

Gallbladder:

- Primary indication for surgery: strong suspicion of malignancy in the gallbladder.

- Gallbladder removed as part of more extensive surgery, a so-called incidental cholecystectomy.

- The presence of a polyp of >10 mm on preoperative imaging.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2018
Enrollment:	8924
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-04-2018
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	NL6963
NTR-old	NTR7151

Register	ID
Other	ZonMw : 843002822

Study results