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

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23801

Bron
NTR

Verkorte titel
FANCY

Aandoening

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

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

Ondersteuning

Primaire sponsor: Academic Medical Center
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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)

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart

(Verwachte) startdatum:	01-05-2018
Aantal proefpersonen:	8924
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-04-2018
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	NL6963
NTR-old	NTR7151
Ander register	ZonMw : 843002822

Resultaten