Stapled or endloop closure of the appendiceal stump in laparoscopic appendectomy. A multicenter blinded randomised trial

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Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON34175

Source
ToetsingOnline

Brief title
STELLA

Condition

- Gastrointestinal inflammatory conditions
- Gastrointestinal therapeutic procedures

Synonym
appendicitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Industrie,Johnson & Johnson

Intervention

Keyword: appendectomy, endoloop, endostapler, laparoscopic

Outcome measures

Primary outcome

The primary outcome parameters are superficial and intra-abdominal infections.

Superficial trocar wound infections demand opening of the wound and additional

wound care. After discharge, patients will visit the outpatient department more

frequently and return to daily activities is delayed until sepsis has resolved.

Intra-abdominal abscesses will require percutaneous drainage or surgery

resulting in prolonged hospital stay or readmission after discharge.

Secondary outcome

Postoperative quality of life at two, four and twelve weeks (SF-36, EQ-5D)

operating time, conversion rate, overall morbidity, hospital stay, return to

work or school, direct and indirect medical costs (direct: equipment, operating

time, infectious complications and indirect: return to work, daily activity) .

Study description

Background summary

Appendectomy for acute appendicitis is a high volume operation worldwide. In the Netherlands only, 16,000 appendectomies are performed for acute appendicitis.
Appendectomy is affecting particularly young patients and is mostly performed by junior surgeons on call.

A trend towards an increasing penetration of the laparoscopic appendectomy is apparent supported by the conclusions of the last update of the Cochrane review on laparoscopic versus open appendectomy. 1
Although the surgical technique of laparoscopic appendectomy is well established, controversy exists regarding the closure of the stump. In the early days the appendix stump was closed using endoloops, while nowadays some advocate the use of the much more expensive endostapler. The endostapler might be associated with a shorter learning curve, shorter operating time, reduced complexity of the procedure, less faecal spill and a more secure closure of the appendix stump at the expense of higher costs of disposable instruments (+/- 700¤). The incidence of intra-abdominal abscesses (4.2%) and wound infections (0.5%) is small but significant, and can lead to reinterventions, additional treatment and prolonged hospital stay. Appendiceal stump closure might play a role in the incidence of intra-abdominal abscesses. A systematic review regarding this topic concluded that, based on three low quality studies, only wound infection rate and postoperative ileus were reduced using endostaplers. The overall reduction in morbidity and cost effectiveness remained to be solved.
Findings have shown both techniques to be safe, but both entail potential drawbacks. Linear staplers are expensive and require a 12-mm port for their introduction. Metal staples on the stump and in the abdominal cavity can cause adhesion-related short bowel obstruction or formation of pseudopolyps in the caecum2-4.
On the other hand, loops are associated with more manipulation of the stump. Moreover, they can slip, which can potentially lead to more postoperative infections. Loops might be not safe for closure if the base of the appendix is involved in the inflammation. If loops are too tight, they also can cut into the tissue or cause local necrosis, predisposing to stump leakage.

Two published systematic reviews5,6 concluded that there is currently insufficient evidence to choose one strategy above the other because the exact balance between clinical effects and costs is unclear. In a cost-effectiveness study alongside a randomised trial we will determine the clinical effectiveness, quality of life and costs associated with both approaches.
The first objective is to determine whether the routine use of endostaplers for closing the appendiceal stump will lead to a lower incidence of infectious complications (intra-abdominal abscess, wound infection), compared to loop closure. The second objective is to determine whether there is a difference in health related quality of life between patients in both treatment groups. Thirdly we aim to prove that endostapling is the easier approach in the sense that it leads to fewer laparoscopic complications, fewer conversions to open surgery, shorter operating time, and shorter hospital stay. As a fourth, the cost effectiveness of both approaches will be calculated to prove that a routine use of endostaplers for the appendiceal stump is more cost-effective compared to loop closure by relating the incidence of infectious complications with the associated direct and indirect costs.

Study objective

The first objective is to determine whether the routine use of endostaplers for closing the appendiceal stump will lead to a lower incidence of infectious complications (intra-abdominal abscess, wound infection), compared to loop closure. The second objective is to determine whether there is a difference in health related quality of life between patients in both treatment groups. Thirdly we aim to prove that endostapling is the easier approach in the sense that it leads to fewer laparoscopic complications, fewer conversions to open surgery, shorter operating time, and shorter hospital stay. As a fourth, the cost effectiveness of both approaches will be calculated to prove that a routine use of endostaplers for the appendiceal stump is more cost-effective compared to loop closure by relating the incidence of infectious complications with the associated direct and indirect costs.

Study design

The cost-effectiveness of laparoscopic appendectomy by both approaches will be studied in a randomised multicenter study. Patients eligible for laparoscopic appendectomy fulfilling the in- and exclusioncriteria are randomised intraoperatively via the trial website for either loop or endostapler closure of the appendix stump. The trial can be performed in a blinded setting. The operating team is the only one that knows what technique has been applied. Nursing and medical staff are blinded for the type of appendix closure.

Intervention

Laparoscopic appendectomy with either stomp closure with use of the endostapler or with the use of endoloops. The procedure is performed according to the Best Practice Guidelines of the Working Group Endoscopic surgery. In the stapling group one 11-12mm disposable trocar and endostapler is required additionally.

Study burden and risks

Not applicable

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patient eligible for laparoscopy
Clinical suspicion for acute appendicitis
Appendicitis on ultrasound, CT or MRI

Exclusion criteria

Perforation of the appendiceal base
Inflammation of the caecum

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2010
Enrollment:	1200
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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
CCMO	NL32725.018.10