Stapler or endoloop closure of the appendiceal stump in laparoscopic appendectomy.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21074

Source
Nationaal Trial Register

Brief title
STELLA

Health condition

Appendicitis
Appendectomy
Appendicectomy
Laparoscopic appendectomy
Appendectomie
Laparoscopische appendectomie

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Amsterdam
Source(s) of monetary or material Support: Investigator-initiated

Intervention

Outcome measures

Primary outcome

Superficial and intra-abdominal infections.

Secondary outcome

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

2. Operating time;

3. Conversion rate;

4. Overall morbidity;

5. Hospital stay;

6. Return to work or school;

7. Direct and indirect medical costs (direct: equipment, operating time, infectious complications and indirect: return to work, daily activity).

Study description

Background summary

Laparoscopic appendectomy is the treatment of choice for appendicitis provided sufficient laparoscopic expertise is available. Infectious complications (wound infection and intra-abdominal abscesses) following laparoscopic appendectomy are however not uncommon and can lead to reinterventions, additional treatment and prolonged hospital stay. A safer and easier stump closure technique using an endostapler rather than the standard loop closure has shown to be effective in reducing the number of infections complications but is associated with higher costs (+/- 700€). In a cost-effectiveness multicenter study alongside a randomized trial we will determine the clinical effectiveness, quality of life and costs associated with both approaches.

Primary outcome parameters are superficial and intra-abdominal infections. Secondary outcome parameters are postoperative quality of life at 2, 4 and 12 weeks (SF-36, EQ-5D) operating time, conversion rate, overall morbidity, hospital stay, return to work or school, direct and indirect medical costs. A sample size of 600 patients per treatment arm will be able to detect a difference in superficial and intra-abdominal infections from 8% in the standard loop group to 4% in the endoloop closure group.

Study objective

Superficial and intra-abdominal infections: 8% in the standard loop group to 4% in the endoloop closure group.

Study design

Follow-up at two, four and twelve weeks.

Intervention

1. Laparoscopic appendectomy with endostapled stump closure;

2. Laparoscopic appendectomy with endolooped stump closure.

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Eligibility criteria

Inclusion criteria

Acute appendicitis.

Exclusion criteria

1. Perforation of the appendiceal base;

2. Inflammation of the caecum.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-09-2010
Enrollment:	1200
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-04-2010
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	NL2165
NTR-old	NTR2289
Other	ZonMW : 80-82310-97-10035
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A