

Elective laparoscopic appendectomy for chronic right lower abdominal pain; outcome of a prospective randomised double-blind controlled surgical trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21065

Source

NTR

Brief title

N/A

Health condition

1. Abdominal pain (NLD: buikpijn);
2. Appendectomy (NLD: blinde darmverwijdering);
3. Laparoscopy (NLD: kijkoperatie);
4. Chronic appendicitis (NLD: chronische blinde darmontsteking);
5. Appendicopathy (NLD: zieke blinde darm).

Sponsors and support

Primary sponsor: dr. RMH Roumen, PhD, MD, surgeon

Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

The primary outcome measure was pain scored by the blinded patient at 6 months postoperatively in the presence of the still blinded surgical resident.

Secondary outcome

The secondary outcome parameter was the relation between clinical improvement and histopathological findings of the removed appendices.

Study description

Background summary

Background:

It is questionable whether elective appendectomy can effectively reduce pain in persistent or recurrent right lower abdominal quadrant pain due to chronic or recurrent appendicitis.

Methods:

A single centre randomised double-blind sham surgery controlled clinical trial studied the effects of elective laparoscopic appendectomy on postoperative pain perception in selected patients with persistent or recurrent lower abdominal quadrant pain on abdominal pain level at 6 months postoperatively. Secondary outcome was the relation between clinical response and the appendix' histopathology. The analysis was performed on an intention-to-treat basis. Pain scores were compared using a Fisher's exact test.

Results:

Forty patients were randomised, 18 patients had a laparoscopic appendectomy and 22

patients had a laparoscopic inspection only. The postoperative pain scores were significantly different favouring appendix removal ($p < 0.01$). Relative risk calculations indicated a 2.4 fold (95% CI: 1.3 – 4.0) greater chance of improving or becoming pain free after laparoscopic appendectomy. The number needed to treat was 2.2 patients (95% CI: 1.5 – 6.5). However, there was no significant relation between postoperative pain scores and histopathology findings.

Conclusions:

Chronic or recurrent appendicitis is a realistic clinical entity that can be treated successfully by elective appendectomy leading to significant pain reduction in properly selected cases. Histopathology of the removed appendix does not contribute to the diagnosis.

Study objective

Elective laparoscopic appendectomy is a usefull procedure in patients with chronic or recurrent right lower abdominal pain.

Study design

N/A

Intervention

Appendectomy by laparoscopy or not.

Contacts

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Eligibility criteria

Inclusion criteria

1. Between 15 and 45 years of age;
2. Suffering from chronic or recurrent right lower abdominal quadrant pain for more than three months;
3. Experience of continuous pain, or should have endured at least one pain attack in the month prior to inclusion.

Exclusion criteria

1. (A history of) Chronic back pain;
2. Previous abdominal surgery (with the exception of diagnostic laparoscopies or a laparoscopic sterilization);
3. Specific gastro-intestinal entities (such as inflammatory bowel disease);
4. Gynaecological disease (all female patients consulted a gynaecologist).

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-1994
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion	
Date:	12-04-2007
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	NL930
NTR-old	NTR955
Other	:
ISRCTN	ISRCTN48831122

Study results

Summary results

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Br J Surg. 2008 Feb;95(2):169-74.