

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

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21065

Bron

NTR

Verkorte titel

N/A

Aandoening

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).

Ondersteuning

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

Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Appendectomy by laparoscopy or not.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-09-1994
Aantal proefpersonen:	40
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	12-04-2007
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	NL930
NTR-old	NTR955
Ander register	:
ISRCTN	ISRCTN48831122

Resultaten

Samenvatting resultaten

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