

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

Submission date 30/05/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/05/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 11/04/2008	Condition category Signs and Symptoms	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR955

Study information

Scientific Title

Elective laparoscopic appendectomy for chronic right lower abdominal pain

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval was received from the local medical ethics committee (Medisch Ethische Toetsings Commissie). The study was considered in 1993 and approved in 1994 (ref: 93-35).

Study design

Randomised, double blinded, placebo controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic right lower abdominal pain

Interventions

Appendectomy by laparoscopy or not.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s)

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

Completion date

01/11/2004

Eligibility**Key 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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

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

Date of first enrolment

01/09/1994

Date of final enrolment

01/11/2004

Locations**Countries of recruitment**

Netherlands

Study participating centre

MÁxima Medisch Centrum

Veldhoven

Netherlands

5500 MB

Sponsor information

Organisation

Maxima Medical Centre (The Netherlands)

ROR

<https://ror.org/02x6rcb77>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Maxima Medical Centre (The Netherlands)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/02/2008		Yes	No