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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

Registration date
30/05/2007

Overall study status
Completed

Last Edited
11/04/2008

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure

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

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

Overall study start date
01/09/1994

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

Age group
Adult

Sex
Not Specified

Target number of participants
40

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)

Sponsor details
Department of General Surgery
P.O. Box 7777
Veldhoven
Netherlands
5500 MB

Sponsor type
Hospital/treatment centre

Website
http://www.mmc.nl/

ROR
https://ror.org/02x6rcb77

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Maxima Medical Centre (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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