

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

<b>Submission date</b> 30/05/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/05/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/04/2008	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Rudi Roumen

### Contact details

MÁxima Medisch Centrum  
Department of Surgery  
P.O. Box 7777  
Veldhoven  
Netherlands  
5500 MB  
+31 (0)40 8888556  
r.roumen@mmc.nl

## 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?
<a href="#">Results article</a>	Results	01/02/2008		Yes	No