Diverticulitis Recurrences or Continuing symptoms : Operative versus Conservative Treatment, A MULTICENTER RANDOMISED CLINICAL TRIAL

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The objective is to compare the outcome of elective surgery to conservative management for patients with persisting abdominal complaints after an episode of diverticulitis and/or frequently recurring diverticulitis (within one year).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diverticular disorders
Study type	Interventional

Summary

ID

NL-OMON39335

Source
ToetsingOnline

Brief title
DIRECT-trial

Condition

- Diverticular disorders

Synonym
diverticulitis, inflammation of outpouchings in the colonic wall

Research involving
Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: conservative, Diverticulitis, operative, persisting, recurrence, recurrent

Outcome measures

Primary outcome

Quality of life measured by the Gastro-intestinal Quality of Life Index,

Shortform-36, EuroQol-5D, ROME III vragenlijst and VAS.

Secondary outcome

- Mortality

- Morbidity

- Recurrence rate

- Total in-hospital costs (including that of subsequents episodes), as well as

costs related to sick leave from paid work and health care consumption.

Study description

Background summary

Persisting abdominal complaints are common after an episode of diverticulitis treated conservatively. Furthermore, some patients develop diverticulitis recurrences within a year These two groups of patients suffer greatly from their disease impairing quality of life and increasing costs due to multiple specialist consultations, pain medication and sick-leave from paid work.
Both conservative and operative management of patients with persisting abdominal complaints after an episode of diverticulitis and/or frequently recurring diverticulitis (within one year) are applied. However, direct comparison by a randomised controlled trial is necessary to determine which is superior in relieving symptoms, optimalising QoL, minimising costs and preventing diverticulitis recurrences against acceptable morbidity and mortality associated with surgery or the occurrence of a complicated recurrence after conservative management.
We, therefore, constructed a randomised clinical trial comparing these two

treatment strategies.

Study objective

The objective is to compare the outcome of elective surgery to conservative management for patients with persisting abdominal complaints after an episode of diverticulitis and/or frequently recurring diverticulitis (within one year).

Study design

Multicenter randomised clinical trial with a follow-up of 1 year.

Intervention

Patients randomised for conservative treatment are treated according to the current daily practice (antibiotics, analgetics and/or expectant management). Patients randomised for elective resection will undergo an elective resection of the affected colon segment. Preferably, a laparoscopic approach is used.

Study burden and risks

Burdens:
- The filling out of the quality of life questionnaires. The filling out of these surveys will take approximately (5x20) 150 minutes of the patient*s time.
- Patients are asked to revisit their local hospital to sign the informed consent. Baseline data will also be collected. This will take 10 minutes.
- The possible, but unlikely, unfavorable outcome of elective resection.
- Randomisation may be a burden giving the fact that patients are subjected to fate for treatment allocation.

Benefits:
The potential benefits of participation in this study for this specific group of patients is a potential final answer to the discussion about the optimal treatment for patients with persisting abdominal symptoms after a diverticulitis episode treated conservatively.
The close follow-up regarding objective and subjective outcome of treatment in the studied subjects is also likely to be beneficial.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age 18-75 years.
- A well documented (CT-scan, sonography or endoscopy) previous episode of diverticulitis.
- Patients presenting with either persisting abdominal complaints and/or frequently recurring diverticulitis after an episode of diverticulitis.
Persisting abdominal complaints may include patients with:
- continuing lower left abdominal pain AND/OR persistent change in bowel habits AND/OR persistent blood loss.
- Symptoms must exist longer than 3 months after a previous episode of diverticulitis.
- Symptoms must be accompanied by changes in the colonic wall on a recent CT-scan, sonography or endoscopy.
Frequently recurring diverticulitis is defined as:
- A total of three or more in-hospital presentations for an episode of diverticulitis within 2 years. As described previously, (at least) one episode must be well documented (CT-scan, sonography or endoscopy).
- A minimal interval of 3 months between the episodes is mandatory.
- ASA I-III

Exclusion criteria

- Patients with elective or emergency surgery for acute diverticulitis in the past.
- Patients with an absolute operation indication (perforation with purulent/fecal peritonitis, symptomatic bowel stenosis or fistula).
- Patients with colorectal malignancies.
- Patients with a psychiatric disease or other conditions making them incapable of filling out the questionnaires or completing the objective follow up tests.
- Patients in ASA class III who are at high risk for per- and postoperative complications due o severe co-morbidity as regarded by the surgeon and/or the patients specialists

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-06-2010
Enrollment:	214
Type:	Actual

Ethics review

Approved WMO

Date:	15-12-2008
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	17-04-2009
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-01-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-03-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-04-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	31-05-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-06-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-07-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-07-2010
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-07-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-09-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-09-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-11-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-12-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-12-2010
Application type:	Amendment
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Approved WMO Date:	24-01-2011
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Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	01-02-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-02-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-05-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-06-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-09-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-09-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-11-2011
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Approved WMO Date:	15-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

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Approved WMO Date:	31-01-2012
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Approved WMO Date:	13-09-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-09-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-11-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-07-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL24903.100.08