A multicenter randomized clinical trial investigating the cost-effectiveness of treatment strategies with or without antibiotics for uncomplicated acute diverticulitis.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27328

Source
Nationaal Trial Register

Brief title
DIABOLO trial

Health condition

Diverticulitis, antibiotics, observation

Sponsors and support

Primary sponsor: Academic Medical Center, department of Surgery
Source(s) of monetary or material Support: ZonMw, grant number 80-82310-97-10039
Maag Lever Darm Stichting, grant number WO 08-54

Intervention

Outcome measures

Primary outcome

The primary endpoint is time-to-full-recovery with a follow-up period of 6 months. Recovery is defined by all of the following criteria: discharged from the hospital (out-patient), normal diet (defined by tolerating vast food and more than 1L of fluid orally), temperature < 38.0 °C, and VAS pain score < 4, with no use of daily pain medication and resuming to pre-illness working activities; as assessed by questionnaires and an out-patient clinic visit.

Secondary outcome

1. Direct and indirect medical costs at 6 months follow-up;

2. Occurrence of complicated diverticulitis defined as abscess, perforation, stricture and/or fistula and need for percuteaneas drainage and\or operation;

3. Antibiotic resistance/sensitivity;

4. Morbidity, like urinary tract infection, pneumonia, etc;

5. Mortality;

6. Readmission rate and recurrence rate at 12 and 24 months follow-up;

7. Changes in health status and valuation over time will be measured using generic and disease specific quality of life questionnaires (Euro-Qol 5D, Short Form 36 (SF-36) and the Gastro-intestinal Quality of Life Index (Giqli)) on admission and after 3, 6, 12 and 24 months.

Study description

Background summary

Rationale/background:

The prevalence of colonic diverticular disease is increasing in Western countries. Approximately 10 to 25% of patients with diverticular disease will eventually develop an episode of acute diverticulitis. Currently conservative treatment often includes antibiotic therapy. This advice lacks sound evidence and is merely based on experts' opinion. An old clinical dogma is being clarified with this randomized trial.

Objective:

Primary objective is to evaluate whether or not using antibiotics reduces to time to full recovery of an attack of uncomplicated (mild) diverticulitis. Secondary objectives are to evaluate complications, quality of life, readmission rate, recurrence rate, medical and non-medical costs, and antibiotic resistance/sensitivity in both groups.

Study design:

A randomized, open label, multicenter clinical trial comparing treatment of acute uncomplicated diverticulitis with antibiotics to observation and supportive care alone.

Study population:

Patients 18 years or older are eligible for inclusion if they have a diagnosis of acute uncomplicated diverticulitis as demonstrated by imaging. Only patients with stages 1a and 1b according to Hinchey’s classification or "mild" diverticulitis according to the Ambrosetti criteria are included.

Intervention:

Conservative strategy with antibiotics: supportive measures and at least 48 hours of intravenous antibiotics (and therefore admittance to the hospital) and subsequently switch to oral antibiotics if tolerated (total duration of 10 days).

Control:

Liberal strategy without antibiotics: supportive measures only. Observation and oral intake as tolerated. Admittance only if discharge criteria are not met on presentation.

Main study parameters/endpoints:

The primary endpoint is time-to-recovery with a 6-month follow-up period. Secondary endpoints are occurrence of complicated diverticulitis requiring surgery or percutaneous treatment, morbidity, health related quality of life, readmission rate, recurrence rate, medical and non-medical costs, and antibiotic resistance/sensitivity.

Study objective

In the treatment of uncomplicated acute diverticulitis, supportive treatment without antibiotics is a more cost-effective approach than conservative treatment with antibiotics with respect to time-to-recovery as primary outcome.

Study design

N/A

Intervention

Intervention:

1. Conservative strategy with antibiotics: supportive measures and at least 48 hours of intravenous antibiotics (and therefore admittance to the hospital) and subsequently switch to oral antibiotics if tolerated (total duration of 10 days).

The choice of antibiotics is amoxicillin-clavulanate for a total of 10 days. Intravenous administration 3 times a day 1200 mg and switch to oral administration 3 times a day 625 mg after two days and if tolerated. In case of allergy a switch will be made to the combination of ciprofloxacin and metronidazole. In case of intravenous administration ciprofloxacin 2 times a day 400 mg and metronidazole 3 times a day 500 mg. In case of oral administration ciprofloxacin 2 times a day 500 mg and metronidazole 3 times a day 500 mg.

2. Control:

Liberal strategy without antibiotics: supportive measures only. Observation and oral intake as tolerated. Admittance only if discharge criteria are not met on presentation.

Contacts

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Eligibility criteria

Inclusion criteria

1. Only left-sided uncomplicated (mild) acute diverticulitis;

2. Clinical suspicion of acute diverticulitis. For acute diagnostic work-up: ultrasound or CT proven diverticulitis. In the case of diverticulitis-negative ultrasound in clinically suspected patients an intravenous contrast-enhanced CT scan is mandatory for confirmation of diverticulitis or exclusion of other pathology. CT for Hinchey/Ambrosetti classification (which is a CT-based classification system) is needed for all patients, but can be delayed 1 day in those with ultrasound diagnosis. Staging diverticultis is defined according the modified Hinchey/Ambrosetti staging, only stages 1a and 1b and "mild" diverticulitis (1a Confined pericoloc inflammation, 1b Confined small (smaller than 5cm) pericolic abscess) are included. In the attachments we have added a flow chart, showing systematically the inclusion criteria and the following steps after inclusion;

3. All patients with informed consent.

Exclusion criteria

1. Previous radiological (ultrasound and/or CT) proven episode of diverticulitis;

2. Colonic cancer;

3. Inflammatory bowel disease (ulcerative colitis, Crohn's disease);

4. Hinchey stages 2, 3 and 4 or "severe" diverticulitis according to the Ambrosetti criteria, which require surgical or percutaneous treatment;

5. Disease with expected survival of less than 6 months;

6. Contra-indication for the use of the study medication (e.g. patients with advanced renal

failure or allergy to antibiotics used in this study);

7. Pregnancy, breastfeeding;

8. ASA (American Society of Anaesthesiologists) classification > III;

9. Immunocompromised patients;

10. Clinical suspicion of bacteraemia (i.e. sepsis);

11. The inability of reading/understanding and filling in the questionnaires;

12. Antibiotic use in the 4 weeks before admittance.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-01-2010
Enrollment:	534
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-10-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 32858
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1951
NTR-old	NTR2069
CCMO	NL29615.018.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON32858

Study results

Summary results
N/A