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

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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...

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

Summary

ID

NL-OMON32858

Source
ToetsingOnline

Brief title
DIABOLO trial

Condition

- Diverticular disorders

Synonym
Complicated diverticular disease, infection of diverticula

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW,Maag Lever en Darm Stichting

Intervention

Keyword: Antibiotics, Diverticulitis, Observation, Time to recovery

Outcome measures

Primary outcome

The primary endpoint is time-to-recovery with a 6-month follow-up period.

Secondary outcome

Secondary endpoints are time to discharge from hospital, 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 description

Background summary

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. With conservative treatment many patients receive 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.

Study 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.

Intervention

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). Discharge when the discharge criteria are met.

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

Study burden and risks

Both treatment regimens in this study are commonly used in the Netherlands and are considered standard of care. The investigational products used in the study have been widely used for a long time already and toxicity and possible side effects are well documented. Treatment of uncomplicated diverticulitis with these antibiotics is common practise in most countries. The risk of omitting antibiotics is probably very low but an independent safety commission closely monitors the adverse effects after every 25 patients. The only difference compared to standard treatment is patients have to fill out three quality of life questionnaires on admission and after 3, 6, 12 and 24 months and feces for culture, so the additional burden for participants is considered minimal.

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

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 are included;
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. Contraindication 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:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-06-2010
Enrollment:	533
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	nvt.
Generic name:	Amoxicillin-clavulanate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	nvt.
Generic name:	Ciprofloxacin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	nvt.
Generic name:	Metronidazole
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	17-09-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-06-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27328
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2009-015004-26-NL
CCMO	NL29615.018.09
OMON	NL-OMON27328