

Randomised controlled trial of oral versus intravenous therapy for clinically diagnosed acute uncomplicated diverticulitis

Submission date 24/03/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 11/04/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 11/04/2008	Condition category Digestive System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Paul Ridgway

Contact details
Department of Surgical Oncology
Room 3-130
Princess Margaret Hospital
610 University Ave
Toronto
Canada
M5G 2M9

Additional identifiers

Study information

Scientific Title

Study objectives

Acute uncomplicated diverticulitis is a disease where outpouchings or blisters (termed Diverticulae) of the large bowel become inflamed resulting in pain and tenderness in the lower abdomen. Acute uncomplicated diverticulitis is currently treated with antibiotics although whether the antibiotics should be given through the veins or via the mouth is not known. Answering this question may allow treatment of the condition as an outpatient in the future.

Diverticulosis affects 5% of western society by the fifth decade, its prevalence increasing to over 50% in the ninth. As less than a quarter of acute admissions necessitate surgery, medical therapy remains the mainstay of management in the majority of cases. There are no prospective data to guide the identification of a specific cohort which may be managed with an oral antibiotic regimen, nor the efficacy of a specific antibiotic regimen.

The authors hypothesise that an oral antibiotic and fluid regimen is equally effective as intravenous antibiotics and 'bowel rest' in acute uncomplicated diverticulitis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Waterford Regional Ethics Board in 2002.

Study design

Multi-centre randomised controlled trial.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute uncomplicated diverticulitis

Interventions

Two intervention arms:

Intravenous arm: Intravenous ciprofloxacin (400 mg twice a day [BID]) and metranidazole (500 mg three times a day [TID]) with bowel rest for at least the first 24 hours.

Oral arm: Oral ciprofloxacin (500 mg BID) and metranidazole (400 mg TID) without complete bowel rest.

Duration of the interventions was equivalent to the length of stay, with a maximal antibiotic duration decided by the attending physician, typically 7-10 days.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Ciprofloxacin and metranidazole

Primary outcome(s)

Resolution of symptoms. Three surrogates were used:

1. Resolution of left iliac fossa tenderness, assessed by the Wexford tenderness score (a locally validated score), daily assessment while an in-patient
2. Length of stay
3. Failure of oral therapy (requiring supplemental parenteral therapy). Follow-up: Until confirmatory/ refuting lower gastrointestinal (GI) series (endoscopic or contrast). Where such a test was not performed, follow-up to last out-patient appointment

Key secondary outcome(s)

The following were evaluated as potential surrogates for resolution:

1. Serial erythrocyte sedimentation rate (ESR). Follow-up: Until confirmatory/ refuting lower GI series (endoscopic or contrast). Where such a test was not performed, follow-up to last out-patient appointment
2. C reactive protein (CRP). Follow-up: Until confirmatory/ refuting lower GI series (endoscopic or contrast). Where such a test was not performed, follow-up to last out-patient appointment
3. White cell count (WCC). Follow-up: Until confirmatory/ refuting lower GI series (endoscopic or contrast). Where such a test was not performed, follow-up to last out-patient appointment
4. Temperature charts, daily assessment while an in-patient

Completion date

31/05/2004

Eligibility

Key inclusion criteria

1. Patients presented with a clinical syndrome of left iliac fossa pain and local tenderness (Hinchey type I and II)
2. Both men and women

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Key exclusion criteria

1. Those with complicated Diverticulitis (Hinchey III and IV)
2. Those in Septic Shock
3. Allergies to antibiotics used in the trial
4. Hepatic or Renal insufficiency
5. Diagnosis is not clear
6. Co-morbid conditions necessitating prolonged hospital stay
7. Pregnant women or women who are breast feeding

Date of first enrolment

01/12/2002

Date of final enrolment

31/05/2004

Locations

Countries of recruitment

Canada

Ireland

Study participating centre**Department of Surgical Oncology**

Toronto

Canada

M5G 2M9

Sponsor information

Organisation

Wexford General Hospital (Ireland)

ROR

<https://ror.org/00bbdze26>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Wexford General Hospital, Department of Surgery (Ireland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration