

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

<b>Submission date</b> 24/03/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 11/04/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 11/04/2008	<b>Condition category</b> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# 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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

### 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 measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

01/12/2002

## **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

**Age group**

Not Specified

**Sex**

Both

**Target number of participants**

76

**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)

**Sponsor details**

Department of Surgery

-

Ireland

Wexford

**Sponsor type**

Hospital/treatment centre

**ROR**

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

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Wexford General Hospital, Department of Surgery (Ireland)

## **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