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

Submission date 24/03/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 11/04/2008	**Overall study status** Completed	
Last Edited 11/04/2008	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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