

Randomised study with ciprofloxacin in acute pancreatitis

Submission date 04/02/2008	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 16/04/2008	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 16/04/2008	Condition category Digestive System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Eduardo Jaurrieta

Contact details
Joan Fabregat
Servei de Cirurgia General i Digestiva,
Unitat Cirurgia Hepatobilio-Pancreàtica i Trasplantament Hepàtic
Hospitalet de Llobregat
Barcelona
Spain
08907

Additional identifiers

Protocol serial number
CGD001/98

Study information

Scientific Title
A double-blind, placebo-controlled trial of ciprofloxacin prophylaxis in patients with acute necrotising pancreatitis

Acronym

CIPRONAP

Study objectives

Our aim was to assess the effects of intravenous prophylactic ciprofloxacin in the incidence of infected necrosis and mortality in patients with necrotising pancreatitis, compared to a control population.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Ethics Committee of the L'Hospitalet de Llobregat (Spain) on the 12th December 1998 (ref: 129/98).

Primary study design

Interventional

Study design

Prospective, randomised, placebo-controlled, double blind study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute pancreatitis

Interventions

All patients with acute pancreatitis suspected to have the severe form of the disease underwent a dynamic contrast-enhanced CT scanning within 48 - 72 hours of admission. When the CT showed a pancreatic necrosis patients signed a written consent, and were randomly assigned to receive one of the below:

1. Prophylactic antibiotic treatment: 300 mg ciprofloxacin every 12 hours for 10 days (n = 22)
2. Placebo (n = 19)

All patients were treated medically on admission (aggressive fluid resuscitation along with electrolyte imbalance, complete avoidance of oral intake, pain control and total parenteral nutrition). Patients with organ failure were followed in the intensive care unit (ICU). When infected necrosis was clinically suspected, a CT-guided fine-needle aspiration (FNA) followed by a Gram stain and a bacteriologic culture was carried out. If infection could be diagnosed through these procedures, we indicated surgical treatment. Further indications for surgery were: diagnostic doubt, organ failure despite intensive medical treatment and symptomatic sterile necrosis (defined as persistent abdominal pain or inability to eat after 4 to 6 weeks of medical management).

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Ciprofloxacin

Primary outcome(s)

To determine whether prophylaxis with intravenous ciprofloxacin could reduce the incidence of infected pancreatic necrosis.

Key secondary outcome(s)

Effects on:

1. Mortality rate
2. Extra-pancreatic infections
3. Surgical treatment, its timing and the re-operation rate
4. Development of organ failure
5. In-hospital as well as intensive care unit (ICU) length of stay

Completion date

31/12/2003

Eligibility**Key inclusion criteria**

All adult patients of either sex:

1. Without previous antibiotic treatment
 2. With detectable pancreatic necrosis in a contrast-enhanced computed tomography (CT) scan
- 25 performed within 48 - 72 hours of admission

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Antibiotic allergy
2. Clinical evidence of sepsis on admission

Date of first enrolment

01/05/1999

Date of final enrolment

31/12/2003

Locations

Countries of recruitment

Spain

Study participating centre

Joan Fabregat

Barcelona

Spain

08907

Sponsor information

Organisation

Hospital Universitari De Bellvitge (Spain)

ROR

<https://ror.org/00epner96>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Bellvitge Hospital (Spain)

Funder Name

No grant nor payment from the pharmaceutical industry.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration