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Randomised study with ciprofloxacine in acute pancreatitis

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

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
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).

Study design
Prospective, randomised, placebo-controlled, double blind study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

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

Overall study start date
01/05/1999

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

Age group

Adult

Sex
Both

Target number of participants
80

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)

Sponsor details
Feixa Llarga S.N.
Hopsitalet de Llobregat
Barcelona
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08907

Sponsor type
University/education

Website

http://www.csub.scs.es

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

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