

Randomised, multicentre, controlled trial comparing oral norfloxacin versus intravenous ceftriaxone in the prevention of bacterial infections in cirrhotic patients with severe liver failure and gastrointestinal bleeding

Submission date 31/01/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/03/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 01/09/2021	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
99-PBE-MNJF-1

Study information

Scientific Title

Randomised, multicentre, controlled trial comparing oral norfloxacin versus intravenous ceftriaxone in the prevention of bacterial infections in cirrhotic patients with severe liver failure and gastrointestinal bleeding

Acronym

MNJF1

Study objectives

Intravenous ceftriaxone is more effective than oral norfloxacin in reducing the rate of bacterial infections in patients with advanced cirrhosis and upper gastrointestinal bleeding.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was approved by the Ethical Committee of each hospital participating in the study and by the Spanish Drug Agency on 29/12/1999

Study design

Randomised, unblinded, multicentre, controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Advanced cirrhosis and haemorrhage

Interventions

Patients who fulfilled the inclusion criteria were randomly allocated into two groups:

1. Patients in the first group received oral norfloxacin 400 mg every 12 hours for seven days
2. Patients in the second group received intravenous ceftriaxone 1 g per day for seven days

Antibiotics were initiated following the emergency endoscopy and always within the first 12 hours after admission into the hospital. Randomisation was done using consecutively numbered computer-generated envelopes containing treatment assignment. Randomisation was independent at each hospital.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Oral norfloxacin, intravenous ceftriaxone

Primary outcome(s)

The end point of the study was to assess if intravenous ceftriaxone is more effective than oral norfloxacin in reducing the rate of bacterial infections within the first 10 days after the haemorrhage.

Key secondary outcome(s)

To assess the effects of treatment allocation on control bleeding and hospital survival.

Completion date

30/04/2004

Eligibility

Key inclusion criteria

1. Age 18 - 80 years
2. Haematemesis and/or melena within 24 hours prior to inclusion
3. Advanced cirrhosis as defined by the presence of two or more of the following signs of liver failure:
 - 3.1. Severe malnutrition
 - 3.2. Serum bilirubin greater than 3 mg/dl
 - 3.3. Ascites and hepatic encephalopathy (grade 1 or more)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

111

Key exclusion criteria

1. Allergy to cephalosporins or quinolones
2. Presence of any of the following signs of infection:
 - 2.1. Fever greater than 37.5°C
 - 2.2. White blood cell count greater than 15,000 mm³
 - 2.3. Immature neutrophils greater than 500 mm³
 - 2.4. More than 15 leukocytes per field in the fresh urine sediment or data compatible with pneumonia on the chest x-ray

3. Treatment with antibiotics within two weeks prior to the hemorrhage (excluding oral norfloxacin for prophylaxis of spontaneous bacterial peritonitis [SBP])
4. Previously diagnosed advanced hepatocellular carcinoma (one nodule greater than 5 cm, three nodules with one greater than 3 cm or more than three nodules) and human immunodeficiency virus (HIV) infection

Date of first enrolment

01/02/2000

Date of final enrolment

30/04/2004

Locations

Countries of recruitment

Spain

Study participating centre

Hospital Clinic

Barcelona

Spain

00036

Sponsor information

Organisation

Barcelona Hospital Clinic Villarroel (Spain)

ROR

<https://ror.org/02a2kzf50>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Barcelona Hospital Clinic Villarroel (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/10/2006	01/09/2021	Yes	No