ISRCTN52008589 https://doi.org/10.1186/ISRCTN52008589

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/03/2006	**Overall study status** Completed	
Last Edited 01/09/2021	**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

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

Primary study design
Interventional

Study design
Randomised, unblinded, multicentre, controlled trial

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 mm^3
2.3. Immature neutrophils greater than 500 mm^3
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 hepatocelullar 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