ISRCTN25761503 https://doi.org/10.1186/ISRCTN25761503

Primary prophylaxis with ciprofloxacin improves survival and reduces bacterial infections in patients with cirrhosis and ascites

Submission date 19/01/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/02/2007	**Overall study status** Completed	
Last Edited 09/05/2019	**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
01/3045

Study information

Scientific Title
Primary prophylaxis with ciprofloxacin improves survival and reduces bacterial infections in patients with cirrhosis and ascites

Acronym
SBP - Spontaneous Bacterial Peritonitis

Study objectives
The aim of the present study was to assess the efficacy of long-term administration of ciprofloxacin for primary prophylaxis of Spontaneous Bacterial Peritonitis (SBP) in patients with cirrhosis and low protein concentration in ascitic fluid.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The protocol was approved by local ethic committees (ethics committee of Hospital Bonorino Udaondo and Hospital Alejandro Posadas) on the 6th March 2000.

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

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
Cirrhotic patients with ascites

Interventions
Ciprofloxacin 500 mg a day or placebo, oral, during 12 months for intervention group and the control group.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Ciprofloxacin

Primary outcome measure
To assess the efficacy of long-term administration of ciprofloxacin for primary prophylaxis of SBP in patients with cirrhosis and low protein concentration in ascitic fluid.

Secondary outcome measures
To assess the efficacy of long-term administration of ciprofloxacin for primary prophylaxis of other infections and mortality.

Overall study start date
01/03/2000

Completion date
01/12/2005

Eligibility

Key inclusion criteria
Diagnosis of cirrhosis was based in clinical, biochemical, ultrasonographic and histological criteria.

Inclusion criteria were:
1. Aged more than 18 and less than 80 years
2. Total protein in ascitic fluid less than 1.5 g/dl
3. Ability to give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
100 patients (50 in ciprofloxacin group and 50 in placebo group)

Total final enrolment
100

Key exclusion criteria
1. A previous episode of SBP
2. Antibiotics in the previous 30 days
3. Pregnancy
4. Active gastrointestinal bleeding

5. Encephalopathy more than grade two
6. Hepatocarcinoma or other malignancies
7. Allergy to quinolones
8. Serum creatinine more than 3 mg/dl
9. Bacterial infection

Date of first enrolment
01/03/2000

Date of final enrolment
01/12/2005

Locations

Countries of recruitment
Argentina

Study participating centre
Caseros 2061
Buenos Aires
Argentina
1264

Sponsor information

Organisation
The Health Council of Investigation of the Government of Buenos Aires (Argentina)

Sponsor details
Medrano 350
Piso 2
Buenos Aires
Argentina
1179

Sponsor type
Government

Website
http://www.buenosaires.gov.ar/area/salud/cons_investigación

Funder(s)

Funder type
Government

Funder Name
The Health Council of Investigation of the Government of Buenos Aires (Argentina) (ref: 01 /3045)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2008	09/05/2019	Yes	No