

Levofloxacin vs piperacillin/sulbactam and sultamicillin in patients with bacterial cholangitis: A double-blind, randomised study

Submission date 13/02/2008	Recruitment status Stopped	☐ Prospectively registered
		☐ Protocol
Registration date 30/04/2008	Overall study status Stopped	☐ Statistical analysis plan
		☐ Results
Last Edited 22/11/2011	Condition category Infections and Infestations	☐ Individual participant data
		☐ 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

Protocol serial number

LAP-387-HUB-0128-I

Study information

Scientific Title

Acronym

LAPIS

Study objectives

In patients with acute cholangitis the use of broad spectrum penicillin is generally accepted. However, due to increasing resistance and allergic reactions, other antibacterial agents may become necessary. Levofloxacin is characterized by an enhanced activity against pathogens of acute cholangitis and by a sufficient concentration in the bile. To evaluate the clinical efficacy of levofloxacin we perform this prospective randomized trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Technical University of Munich. Date of approval: 23/08/2006

Primary study design

Interventional

Study design

Double-blind, randomised, single-centre controlled trial.

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Bacterial cholangitis

Interventions

Control group: Piperacillin 4 g/sulbactam 1 g intravenously (i.v.) 3 x daily for 2 days, then sultamicillin 0.75 g orally (p.o.) 2 x daily for 2-8 days.

Experimental group: Levofloxacin 0.5 g i.v. 1 x daily for 2 days, additionally 2 x daily placebo (0.9% NaCl), then levofloxacin 0.5 g p.o. 1 x daily for 2-8 days, additionally 1 x daily placebo capsule.

Trial stopped as of 28/09/2011 due to poor recruitment.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Levofloxacin, piperacillin, sulbactam and sultamicillin.

Primary outcome(s)

Number of days in hospital (in-patient)

Key secondary outcome(s)

1. Change of antibiotic therapy, recorded during the treatment
2. Duration of antibiotic therapy during the interventions
3. Fever, monitored during the treatment
4. Laboratory parameters
5. Complications of antibiotic therapy during the treatment

Completion date

30/04/2009

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility**Key inclusion criteria**

1. Clinical signs of bacterial cholangitis
2. Elevated cholestase parameters
3. Elevated infection parameters
4. Age 18-90 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

90 Years

Sex

All

Key exclusion criteria

1. Potential other cause of infection
2. Pregnancy
3. Psychiatric disease
4. Penicillin incompatibility
5. Fluoroquinolone incompatibility
6. Leucopenia
7. Immunosuppressive medication
8. AIDS
9. Liver cirrhosis

- 10. Microbiological resistance against study medication
- 11. Biliary pancreatitis
- 12. Antibiotic pre-treatment within 48 hour before study inclusion

Date of first enrolment

02/05/2007

Date of final enrolment

30/04/2009

Locations

Countries of recruitment

Germany

Study participating centre

Klinikum rechts der Isar

Munich

Germany

81675

Sponsor information

Organisation

Technical University Munich (Germany)

ROR

<https://ror.org/02kkvpp62>

Funder(s)

Funder type

Industry

Funder Name

Sanofi Aventis (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration