

PILA trial: Levofloxacin vs piperacillin /sulbactam and sultamicillin in patients with acute cholecystitis

Submission date 17/03/2008	Recruitment status Stopped	☐ Prospectively registered ☐ Protocol
Registration date 12/06/2008	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 22/05/2012	Condition category Digestive System	☐ 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
PIL-629-WEB-0128-I

Study information

Scientific Title

Acronym

PILA

Study objectives

In patients with acute cholecystitis 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 cholecystitis and by a sufficient concentration in the bile and gallbladder tissue. To evaluate the clinical efficacy of levofloxacin we perform this prospective randomised trial.

As of 22/05/2012, the anticipated end date of trial has been updated from 30/04/2010 to 16/05/2012.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Technical University of Munich. Date of approval: 04/03/2008.

Primary study design

Interventional

Study design

Double-blind, randomised, single-centre trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute cholecystitis

Interventions

Control group: Piperacillin 4 g or 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 + 2 x daily placebo capsule (0.9% NaCl) for 2 days, then levofloxacin 0.5 g p.o. 1 x daily + 1 x daily placebo capsule for 2 - 8 days.

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)

The following will be monitored during the treatment:

1. Change of antibiotic therapy
2. Duration of antibiotic therapy
3. Fever
4. Laboratory parameters
5. Complications of antibiotic therapy

Completion date

16/05/2012

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility**Key inclusion criteria**

1. Clinical signs of acute cholecystitis
2. Acute cholecystitis identified by transabdominal ultrasound
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. Renal failure

- 7. AIDS
- 8. Liver cirrhosis
- 9. Seizure disorder

Date of first enrolment

01/04/2008

Date of final enrolment

16/05/2012

Locations

Countries of recruitment

Germany

Study participating centre

Klinikum rechts der Isar

Munich

Germany

81675

Sponsor information

Organisation

Technical University of 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