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

Submission date 17/03/2008	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/06/2008	**Overall study status** Stopped	
Last Edited 22/05/2012	**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

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.

Study design
Double-blind, randomised, single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Number of days in hospital (in-patient)

Secondary outcome measures
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

Overall study start date
01/04/2008

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 transabdmonial ultrasound
3. Elevated infection parameters
4. Age 18-90 years

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
142

Key exclusion criteria
1. Potential other cause of infection
2. Pregnancy
3. Psychiatric disease
4. Penicillin incompatibility
5. Fluorochinolon 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)

Sponsor details

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Sponsor type
University/education

Website
http://www.dekanat.med.tum.de

ROR
https://ror.org/02kkvpp62

Funder(s)

Funder type
Industry

Funder Name
Sanofi Aventis (France)

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