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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

LAP-387-HUB-0128-l

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

Study design
Double-blind, randomised, single-centre controlled 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
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 measure
Number of days in hospital (in-patient)

Secondary outcome measures
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

Overall study start date
02/05/2007

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
128 (37 included before trial discontinued)

Key exclusion criteria
1. Potential other cause of infection
2. Pregnancy
3. Psychiatric disease
4. Penicillin incompatibillity
5. Fluorochinolon incompatibillity
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
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Sponsor information

Organisation
Technical University Munich (Germany)

Sponsor details
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Sponsor type
University/education

Website
http://portal.mytum.de/tum/index_html

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