

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

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

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 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)

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