Determining the tissue-penetration of antibiotics into liver cysts.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20974

Source
Nationaal Trial Register

Brief title
PENTAC 2

Health condition

In this explorative pharmakinetics study, our aim is to assess tissue-penetration of antibiotics (ciprofloxacin, co-trimoxazole, doxycycline and piperacillin/tazobactam) into hepatic cysts, to guide therapy for hepatic cyst infections.

Sponsors and support

Primary sponsor: Radboud university medical center
Source(s) of monetary or material Support: Radboud university medical center

Intervention

Outcome measures

Primary outcome

The primary endpoint of the study is the hepatic cyst penetration of ciprofloxacin, co-trimoxazole, doxycycline and piperacillin/tazobactam,defined as the ratio (%) of cyst aspirate concentration (ug/ml) to blood plasma concentration (ug/ml).

Secondary outcome

Day-curve plasma concentrations.

Study description

Background summary

Hepatic cysts are fluid-filled cavities located in the liver parenchyma. Spontaneous cyst infection presents a severe complication of hepatic cystic disease requiring frequent hospitalization, long-term antibiotic treatment, and in some patients, invasive therapies. It is most commonly caused by Escherichia coli strains and first-line treatment is ciprofloxacin. However, 10-47% of Escherichia coli strains in Europe are resistant to fluoroquinolones (e.g. ciprofloxacin) and fluoroquinolones fail in 50% of cyst infections. Even after successful treatment, recurrence is as high as 20%. Highlighting the need for novel (evidence-based) antimicrobial regimens. In addition, evidence that the used antibiotics are able to reach adequate intracystic concentrations is scarce. A previous proof-of-concept study showed no cyst penetration of cefazolin. In this study we want to assess the hepatic cyst penetration capacity of intravenously administered antibiotics (ciprofloxacin, co-trimoxazole, doxycycline and piperacillin/tazobactam) by comparing blood and cyst fluid concentrations in patients undergoing aspiration sclerotherapy for non-infected, large, symptomatic, hepatic cysts.

This explorative single-centre study will investigate the penetration of antibiotics into hepatic cysts, to guide in clinical decision making when faced with spontaneous hepatic cyst infection.

Study objective

Our hypothesis is that piperacillin/tazobactam, ciprofloxacin, co-trimoxazole and doxycycline are able to penetrate hepatic cysts.

Study design

Primary: at aspiration sclerotherapy

Secondary: every 1.5 hours after infusion. (6 times in total)

Intervention

Group 1: ciprofloxacin and piperacillin/tazobactam

Group 2: doxycycline and co-trimoxazole

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

- Age < 18 years

- Indication for aspiration and sclerotherapy (large symptomatic liver cyst)

- Providing informed consent

Exclusion criteria

- History of hypersensitivity to multiple antibiotics, making it impossible to include the patient in one of two treatment groups.

- Use of other drugs with a contra-indication for antibiotic use, making it impossible to include the patient in one of two treatment groups.

- Presence of an arterio-venous fistula, history of mastectomy or lymph node dissection at both extremities.

- Signs of phlebitis, defined as localized skin redness and swelling, at both extremities

- Any current or prior medical condition that may interfere with the conduct of the study or the evaluation of its results in the opinion of the investigator.

- Severe renal impairment (eGFR < 30 ml/min/1,73 m2)

- Use of antibiotics that are going to be administered for the study in the 7 days before aspiration sclerotherapy.

- History of hypersensitivity to multiple antibiotics, making it impossible to include the patient in one of two treatment groups.

- Use of other drugs with a contra-indication for antibiotic use, making it impossible to include the patient in one of two treatment groups.

- Presence of an arterio-venous fistula, history of mastectomy or lymph node dissection at both extremities.

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Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2019
Enrollment:	20
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7290
NTR-old	NTR7499
Other	EudraCT number : 2018-003262-13

Study results