Determining the tissue-penetration of antibiotics into liver cysts.

Gepubliceerd: 25-09-2018 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20974

Bron
NTR

Verkorte titel
PENTAC 2

Aandoening

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.

Ondersteuning

Primaire sponsor: Radboud university medical center
Overige ondersteuning: Radboud university medical center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Primary: at aspiration sclerotherapy

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

Onderzoeksproduct en/of interventie

Group 1: ciprofloxacin and piperacillin/tazobactam

Group 2: doxycycline and co-trimoxazole

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age < 18 years

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

- Providing informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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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Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2019
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten