Assessment of Treatment with Laparoscopic fenestration or Aspiration Sclerotherapy for large symptomatic hepatic cysts (ATLAS): a randomized clinical trial.

Gepubliceerd: 13-11-2020 Laatst bijgewerkt: 15-05-2024

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

Samenvatting

ID

NL-OMON20962

Bron
NTR

Verkorte titel
ATLAS

Aandoening

Polycystic liver disease, autosomal dominant polycystic kidney disease, autosomal dominant polycystic liver disease, liver cysts

Ondersteuning

Primaire sponsor: Radboudumc
Overige ondersteuning: Investigater funded

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter is the PLD-Q score at 4 weeks after treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

SUMMARY
Rationale: Patients with large hepatic cysts(>5cm) may develop symptoms due to distention of Glisson's capsule and/or compression on other abdominal organs. Frequently reported symptoms include abdominal pain, early satiety, nausea, and dyspnea. These symptoms can be captured in the disease-specific Polycystic Liver Disease Questionnaire (PLD-Q), a validated instrument. The treatment of symptomatic liver cysts is aimed to improve symptoms and quality of life by reducing cyst volume. There are two procedures available to treat symptomatic liver cysts: percutaneous aspiration sclerotherapy and laparoscopic fenestration.

In aspiration sclerotherapy, fluid is evacuated from the liver cyst and subsequently the cyst lining is exposed to a sclerosing agent for a limited period of time. Sclerotherapy causes temporary recurrence of cyst fluid after drainage, but subsequently results in a steady decrease of cyst volume in the majority of patients.

In laparoscopic fenestration the liver is exposed through laparoscopic surgery. In this procedure the cyst is punctured and drained followed by resection of extra-hepatic cyst wall.

The safety and efficacy of aspiration sclerotherapy and laparoscopic fenestration have been explored in two recent systematic reviews. No evident conclusion could be drawn because of the retrospective study design in the vast majority of the studies and the heterogeneity among these. A randomized controlled trial is warranted to identify the possible differences in safety and efficacy in aspiration sclerotherapy and laparoscopic fenestration.

Hypothesis: We expect patients treated with laparoscopic fenestration to have better clinical outcome; i.e. a lower PLD-Q score, compared to aspiration sclerotherapy, when measured 4 weeks after the procedure. We expect this difference to become smaller over time (after 6 and 12 months), with loss of statistical significance.

Objective: The main objective is to compare laparoscopic fenestration and aspiration sclerotherapy in patients with large symptomatic hepatic cysts on patient-reported outcomes. This information can be used to assess cost-effectiveness in both treatments.

Study design: A single-center, prospective, randomized clinical superiority trial in which patients will be randomized 1:1 to one of the treatment arms. Patients will be followed for 1 year.

Study population: All patients ≥18 years who are diagnosed with a dominant, simple hepatic cyst (>5 cm in diameter), that are symptomatic (PLD-Q sscore ≥20) and have an indication for treatment (both aspiration sclerotherapy and laparoscopic fenestration) are suitable for inclusion in this study. Only patients that are eligible for both treatments can be included in this study. In particular, patients with multiple cysts (>20 cysts of >1.5 cm) will be excluded as surgery leads to more complications in these patients.

Intervention: Patients will be randomly allocated to either aspiration sclerotherapy or laparoscopic fenestration. Both procedures are performed according to the standard Radboudumc protocols. Aspiration sclerotherapy consists of ultrasound-guided, percutaneous drainage of the cyst with subsequent sclerosation with ethanol. Laparoscopic fenestration consists of standard abdominal laparoscopy in which the large cyst(s) are drained and deroofed.

Main study parameters: The main study parameter is the PLD-Q score at 4 weeks after treatment. Secondary parameters are among others: PLD-Q score at baseline, 6 months and 12 months; liver volume (CT) at baseline and 4 weeks; cyst volume (ultrasound) at baseline, 4 weeks, 6 months and 12 months; complications according to Clavien-Dindo; admission duration, recurrence and re-intervention rates.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: All symptomatic liver cysts patients that are included have an indication for treatment by aspiration sclerotherapy or laparoscopic fenestration. The described follow-up is according to the regular liver cyst treatment local protocol, including site visits, questionnaires and ultrasound. For patients allocated to the aspiration sclerotherapy arm of the study, one additional CT-scan is made at 4 weeks, which would not be standard protocol. In case of an inconclusive ultrasound at 6 months, a CT-scan (without contrast, low-dose) will be performed to measure cyst volume.

In summary, besides random allocation and extra follow-up CT-scan(s), the study forms no extra burden or associated risks. Associated risks in aspiration sclerotherapy are temporary and mild, e.g. local pain. Associated risks in laparoscopic fenestration are bile leakage, ascites, pleural effusion or infections. The number of questionnaire-sets that need to be filled in will be 4-5 (dependent on intermittent recurrence). The number of CT-scans that will be made during the study is 1, 2 or 3, depending on available imaging before screening and need for a CT-scan at 6-months follow-up.

Doel van het onderzoek

We expect patients treated with laparoscopic fenestration to have better clinical outcome; i.e. a lower PLD-Q score, compared to aspiration sclerotherapy, when measured 4 weeks after the procedure. We expect this difference to become smaller over time (after 6 and 12

months), with loss of statistical significance.

Onderzoeksopzet

Baseline, treatment, 1 month after treatment, 6 months after treatment, 12 months after treatment

Onderzoeksproduct en/of interventie

Patients will be randomly allocated to either aspiration sclerotherapy or laparoscopic fenestration. Both procedures are performed according to the standard Radboudumc protocols. Aspiration sclerotherapy consists of ultrasound-guided, percutaneous drainage of the cyst with subsequent sclerosation with ethanol. Laparoscopic fenestration consists of standard abdominal laparoscopy in which the large cyst(s) are drained and deroofed.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Age ≥18 years
• Hepatic cyst characteristics:
o Large (>5 cm),
o Symptomatic (PLD-Q score ≥20),

o Non-parasitic on imaging (US/CT/MRI)
o Non-neoplastic on imaging (US/CT/MRI)
• Providing informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Clinical suspicion of a complicated hepatic cyst (cyst rupture or active cyst infection)
• Cyst is not laparoscopically accessible for surgery
• Cyst is not percutaneously (ultrasound-guided) accessible for aspiration
• More than 20 cysts of >1.5 cm
• Age above 70 years
• ASA IV
• ECOG score >1
• Aspiration sclerotherapy or laparoscopic fenestration of hepatic cysts was performed in the last 6 months.
• Severe renal impairment (eGFR < 30 ml/min/1,73 m2)
• Coagulopathy (spontaneous INR >2 or platelet count < 80 x 109/l)
• Radiologic contrast allergy
• Pregnancy
• 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 (e.g. inability to fill out questionnaires).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2021

Aantal proefpersonen:	70
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 51055
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9057
CCMO	NL75717.091.20
OMON	NL-OMON51055

Resultaten