A nationwide cohort study on benign liver tumors and cysts in the Netherlands

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Benign liver tumors and cysts carry a significant burden on the quality of life in some cases. Apart from impairing symptoms, psychological burden might provide sufficient ground for surgical intervention. There is a variable approach to them…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	Lever- en galwegneoplasmata benigne
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20812

Bron
Nationaal Trial Register

Verkorte titel
BELIVER

Aandoening

- Lever- en galwegneoplasmata benigne

Aandoening

Solid lesions Focal nodular hyperplasia Haemangioma Hepatocellular adenoma Hepatic haemangioendothelioma Cystic lesions Simple hepatic cysts Mucinous cystic neoplasm of the liver and biliary system Intraductal papillary neoplasms of the liver and bile ducts

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: N/a
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

- Overige

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

Change in PROs including severity of symptoms from the start compared to the end of the follow-up period.
PROs: anxiety, fatigue, ability to participate and pain interference using computerized adaptive testing through the Dutch-Flemish Patient-Reported Outcomes Measurement Information System (PROMIS), numerical rating scales for pain (current and most, least, and average pain over a week) and two general health and quality of life questions

Toelichting onderzoek

Achtergrond van het onderzoek

Benign liver tumours and cysts (BLTCs) comprise a heterogeneous group of cystic and solid lesions, including hepatic hemangioma, focal nodular hyperplasia and hepatocellular adenoma. Some BLTCs, for example (large) hepatocellular adenoma, are at risk of complications. Incidence of malignant degeneration or hemorrhage is low in most other BLTCs. Nevertheless, the diagnosis BLTC may carry a substantial burden and patients may be symptomatic, necessitating treatment. The indications for interventions remain matter of debate. The primary study aim is to investigate patient reported outcomes (PROs) of patients with BLTCs, with special regard to the influence of invasive treatment as compared to the natural course of the disease.

Doel van het onderzoek

Benign liver tumors and cysts carry a significant burden on the quality of life in some cases. Apart from impairing symptoms, psychological burden might provide sufficient ground for surgical intervention. There is a variable approach to them throughout the country, but surgical outcomes are comparable.

Onderzoeksopzet

Questionnaire biannually, or if (minimally invasive) intervention occurs at 3, 6 and 12 months postoperatively. Study period October 2021-October 2026, minimal follow-up 2 years

Onderzoeksproduct en/of interventie

N/a

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adult patients (>18 years old) presenting with a common and/or clinically relevant BLTC at participating centers are eligible for inclusion. Clinically relevant BLTCs are defined as all BLTCs potentially eligible for either surgical intervention or follow-up.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Age < 18 years
- Unable to fill in questionnaires

- Unable to comprehend the Dutch language sufficiently
- Severe quality of life impairment by alternate pathology

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Enkelvoudig
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2020
Aantal proefpersonen:	450
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	10-12-2019
Soort:	Eerste indiening
Toetsingscommissie:	nWMO adviescommissie UMC Groningen

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	NL8231
Ander register	METc AMC & METc UMCG : AMC:W19_134 # 19.167 UMCG: 201900292 (2019-269)

Resultaten