

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

Published: 10-12-2019

Last updated: 26-10-2024

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...

Ethical review	Positive opinion
Status	Recruiting
Health condition type	Hepatic and biliary neoplasms benign
Study type	Observational non invasive

Summary

ID

NL-OMON20812

Source

Nationaal Trial Register

Brief title

BELIVER

Condition

- Hepatic and biliary neoplasms benign

Health condition

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

Research involving

Human

Sponsors and support

Primary sponsor: N/a

Source(s) of monetary or material Support: N/A

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

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

Secondary outcome

Surgical outcomes & tumor specific complications

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

N/a

Contacts

Public

Department of Surgery, Amsterdam UMC Location AMC
Alicia Furumaya

020 566 9111

Scientific

Department of Surgery, Amsterdam UMC Location AMC
Alicia Furumaya
Department of Surgery, Amsterdam UMC Location AMC

020 566 9111

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

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.

Exclusion criteria

- Age < 18 years - Unable to fill in questionnaires - Unable to comprehend the Dutch language sufficiently - Severe quality of life impairment by alternate pathology

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-10-2020
Enrollment:	450
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion	
Date:	10-12-2019
Application type:	First submission
Review commission:	nWMO adviescommissie UMC Groningen

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 NL8231

Other METc AMC & METc UMCG : AMC:W19_134 # 19.167 UMCG: 201900292 (2019-269)

Study results