Shared decision making in Perihilar Cholangiocarcinoma and Hepatocellular Adenoma: The SAPACHA study

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The implementation of decision support tools (DCTs) will improve the level of shared decision making in patients with perihilar cholangiocarcinoma and hepatocellular adenoma

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22521

Bron
NTR

Verkorte titel
SAPACHA

Aandoening

Perhilar cholangiocarcinoma en hepatocellular adenoma

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The change in the level of patient involvement during PHC and HCA consultations in which a

treatment decision is to be made, with the DSTs, scored objectively by independent observers with the use of the OPTION-5 instrument.

Toelichting onderzoek

Achtergrond van het onderzoek

Summary

Rationale: Shared decision-making (SDM) is a process in which the best available evidence on possible benefits and harms of the different treatment options and patients' preferences are integrated. SDM requires bidirectional communication between doctors and patients to involve the patient's preference in the eventual treatment decision, thereby respecting the patient's autonomy. The application of SDM is clinical practice might lead to improved affective-cognitive outcomes as well as improved health outcomes and reduced costs. SDM may already be present to some extent, but can often be improved substantially.

Objective: The proposed study aims to improve the participation of patients with hepatocellular adenoma (HCA) and perihilar cholangiocarcinoma in decisions regarding their own treatment with the help of decision support tools (DSTs).

Study design: A multicentre prospective study, consisting of three phases:
1. Baseline measurement of the level of SDM
2. Development of DSTs
3. Introduction of DSTs and post-introduction measurements of the level of SDM.

Study population: All adult patients with a perihilar cholangiocarcinoma of hepatocellular adenoma, visiting the outpatient clinic of a participating surgery and/or gastroenterology department will be asked to participate.

Intervention: In order to improve the level of SDM, various DST. DSTs need to be developed and applied. The use of various DSTs will be compared to patients who receive the standard information from their treating physician (often a surgeon or gastroenterologist) without the use of DSTs. Examples of DSTs are: decision aids, consultation aids and offering shared decision-making training for physicians.

Main study parameters/endpoints: The level of patient involvement during PHC and HCA consultations in which a treatment decision is to be made, with the DSTs, scored objectively by independent observers with the use of the OPTION-5 instrument.

Doel van het onderzoek

The implementation of decision support tools (DCTs) will improve the level of shared decision making in patients with perihilar cholangiocarcinoma and hepatocellular adenoma

Onderzoeksopzet

Follow-up moments: at inclusion, during consultation, immediately after consultation, shortly before intervention

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria
- Age > 18 years
- Newly diagnosed patients with PHC or HCA
- Capable of providing written and oral informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Insufficient understanding of the Dutch language or cognitively unable to complete Dutch questionnaires.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	20-02-2020
Aantal proefpersonen:	38
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

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	NL8399
Ander register	METC AMC : W20_079 #20.107

Resultaten