

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

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON22521

### Source

NTR

### Brief title

SAPACHA

### Health condition

Perihilar cholangiocarcinoma en hepatocellular adenoma

## Sponsors and support

**Primary sponsor:** None

**Source(s) of monetary or material Support:** None

## Intervention

## Outcome measures

### Primary outcome

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.

## Secondary outcome

1. Increase of subjective use of SDM according to patients. This will be evaluated using the SDM Q-9 questionnaire, as measured at baseline and after implementation
2. Increase of subjective use of SDM according to physicians. This will be evaluated using the SDM Q-doc questionnaire, as measured at baseline and after implementation
3. The change in level of quality of life. This will be evaluated using the EORTC QLQ-C30[17] and EORTC QLQ-BIL21[18] questionnaires.
4. The change in level of adherence with the chosen treatment option. The chosen treatment is obtained from the recording and compared with the eventually received treatment obtained from the participating surgeon / gastroenterologist.
5. Decisional conflict, the decisional conflict in patients is scored using the Decisional Conflict Scale (DCS)[19].
6. The level of disease-specific knowledge in patients is scored after consultation with the physician. This is measured by the use of a small questionnaire about the disease and associated treatments.
7. The, change in, duration of the consultation with the physician (i.e. do the implementations change the time of the visit?). The duration of the consultation prior to and after the implementation of the DST is measured and compared using the audiotape of the consultation.
8. The change in experienced anxiety. The change in experienced anxiety is measured using the Visual Analogue Scale for Anxiety (VAS-A scale)[20].

## Study description

### Background summary

#### 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 in 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.

#### **Study objective**

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

#### **Study design**

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

## **Contacts**

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## **Eligibility criteria**

## Inclusion criteria

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

## Exclusion criteria

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

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	20-02-2020
Enrollment:	38
Type:	Anticipated

### IPD sharing statement

**Plan to share IPD:** No

## Ethics review

Not applicable  
Application type:

Not applicable

## 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	NL8399
Other	METC AMC : W20_079 #20.107

## Study results