Preoperative risk stratification in liver and pancreas surgery: comparing predictive risk model with the judgment of the surgeon

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

Samenvatting

ID

NL-OMON26588

Bron
NTR

Verkorte titel
The RISC study

Aandoening

All pancreas, liver or bile duct diseases that require surgery.

Ondersteuning

Primaire sponsor: University Medical Center Utrecht (UMCU), Department of Surgery
Overige ondersteuning: University Medical Center Utrecht (UMCU), Department of Surgery

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To assess whether the available predictive risk models are superior compared to the

clinical judgment of the consultants (surgeons risk assessment) as regards to predicting the risk of postoperative complications and mortality.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The number of patients who are referred to surgery for treatment of (pre) malignant or benign hepatopancreatobiliary (HPB) disease is increasing. This is due to improved surgical techniques and advances in abdominal surgery. Another explanation for the increasing HPB surgery workload is the implementation of centralization to tertiary centres and acceptance of major abdominal surgery as a safe modality in the elderly. Despite the increased experience and advances in HPB surgery, it is still considered high-risk and is often accompanied by low- or high-grade postoperative complications. Furthermore, most of these patients have comorbidities that in turn increase the risk of postoperative complications.

Objectives: The primary objective is to assess whether the available risk score models are superior compared to the clinical judgment of the operating surgeon with regard to predicting the risk of postoperative outcome (morbidity and mortality). Secondary objective is assessment of the inter-observer variability of the consultants risk assessment.

Study design: Prospective observational multicenter study

Study population: Patients > 18 years, who are eligible for open or laparoscopic hepatopancreatobiliary surgery (including all surgical procedures of liver, gallbladder, bile ducts and pancreas; excluding diagnostic laparoscopy)

Intervention: There are no experimental interventions.

Main study parameters/endpoints: The main primary study parameters are the surgical risk assessment, the postoperative complication rate and the postoperative mortality. The postoperative morbidity will be evaluated according to the Clavien-Dindo classification for postoperative complications. Secondary study parameter is the surgical related mortality.

Onderzoeksopzet

Postoperative complications are defined as complications that require surgical, endoscopical or radiological intervention or complications with single/multi organ dysfunction(Clavien Dindo classification grade III/IV)

Operative mortality is defined as in-hospital death (irrespective of the duration of stay) or death occurring within 30 days after discharge.

Onderzoeksproduct en/of interventie

All major/minor open or laparoscopic hepatopancreatobiliary surgery (excluding diagnostic laparoscopy).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients undergoing abdominal surgery for possible malignancy or benign lesions in the pancreas, liver or bile ducts.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients younger than 18 years

2. Adults lacking capacity

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	20-06-2014
Aantal proefpersonen:	289
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-06-2014
Soort:	Eerste indiening

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	NL4407
NTR-old	NTR4649
Ander register	METC UMC Utrecht : 14-325

Resultaten