The Portal venous Content of Microbial Molecules (PoCoMiMo) Study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON51237

Source
ToetsingOnline

Brief title
PoCoMiMo-study

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary neoplasms malignant and unspecified

Synonym
Liver cancer, pancreas cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Het UMCG kanker research fonds

Intervention

Keyword: Bacterial metabolites, Hepatectomy, Microbiome, Portal vein

Outcome measures

Primary outcome

The primary study parameter is the intestinal uptake of microbiome-derived metabolites as defined by their enrichment between arterial (pre-intestinal) and post-intestinal (portal venous) blood samples.

Secondary outcome

Secondary outcomes are the association between intestinal uptake of metabolites with microbial features determined by metagenomic sequencing, and - in the subset of patients undergoing partial liver resection - the rate of hepatic clearance of microbial metabolites between pre-hepatic (portal venous) and post-hepatic (hepatic venous) blood samples in relation to hepatic gene expression of phase I and phase II biotransformation enzymes in a research liver biopsy.

Study description

Background summary

Changes to the composition of the intestinal microbiome are associated with a variety of human cancers and the outcome of cancer treatment, yet the mechanisms via which microbial dysbiosis can contribute to pathogenesis remain poorly defined. Since gut bacteria generally stay confined to the lumen of the intestine, it is assumed that their extra-intestinal effects must be mediated to a large extent by bacteria-derived products that gain access to the host by crossing the epithelial barrier of the gut. Following their absorption from the intestine, microbially-derived metabolites enter the portal venous circulation and hence must pass the liver before entering the systemic circulation. This direct delivery to the liver is significant, since the liver functions as a

metabolic and immunological hub that orchestrates whole-body physiology. The liver is furthermore responsible for detoxifying foreign chemical compounds, which may result in the hepatic clearance of particular microbial metabolites before ever reaching the systemic circulation (first-pass effect). Consequently, in-depth analysis of pre-hepatic, portal venous blood samples can improve our understanding of the molecular mechanisms that integrate gut microbiota and extra-intestinal human physiology.

Study objective

The objective of the PoCoMiMo study is to compare the abundance, and hepatic clearance of microbiota-derived molecules in the portal venous circulation between patients suffering from a primary hepatic malignancy versus those with pancreatic cancer versus living liver donors (healthy controls).

Study design

This is an exploratory, single-centre, case-control study.

Study burden and risks

Participating patients will be asked for a one-time stool collection and a 1-day dietary recall questionnaire, and to consent to the perioperative sampling of 5 ml of portal vein blood and 5 ml arterial blood and - in patients undergoing partial liver resection - 5 ml post-hepatic venous blood and a surgical biopsy from the resected liver tissue.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adult patients undergoing any of the following surgical interventions:
• Partial hepatic resection for an underlying hepatic malignancy
• Pancreaticoduodenectomy for a pancreatic malignancy
• Living donor liver transplantation

Exclusion criteria

Exclusion criteria are as follows:
• Patients who are known to suffer from an active viral infection (e.g. hepatitis B or C)
• Patients with severe portal hypertension
• Patients who cannot provide informed consent due to cognitive impairment or language barrier

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-08-2021
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO

Date:	22-06-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (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
CCMO	NL77185.042.21