

# A prospective trial of the use of CT colonography to screen for colonic neoplasia in patients prior to liver transplantation.

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This study aims to show that CT colonography is feasible in combination with 4-phase CT of the liver in one session, has good diagnostic accuracy and is associated with fewer complications and is therefore the investigation of choice in these...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Malignant and unspecified neoplasms gastrointestinal NEC
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON35188

### Source

ToetsingOnline

### Brief title

CTC colorectal cancer screening prior to liver transplantation.

### Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

### Synonym

colorectal cancer and polyps

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** adenomatous polyps, colorectal cancer, CT colonography, liver transplantation

## Outcome measures

### Primary outcome

technical quality of the scans - feasibility of combined CTC/4 phase CT of the

liver

complications - O2 saturation below 92%, post-procedural pain

### Secondary outcome

n/a

## Study description

### Background summary

Patients with end-stage liver failure entering into a transplant program are screened for the presence of colonic neoplasia. This is currently performed using colonoscopy. However, CT colonography has developed to the point where it is diagnostically equivalent. This patient group also undergoes 4-phase CT of the liver as part of the pre-transplantation screening process and theoretically could be combined with CT colonography in one scanning session. Furthermore colonoscopy in this patient group involves increased risks when compared to the general population, tipping the balance of benefit versus risk towards choosing a non-invasive screening modality that requires no sedation in this patient group. This study aims to show that CT colonography is feasible in combination with 4-phase CT of the liver in one session, has good diagnostic accuracy and is associated with fewer complications and is therefore the investigation of choice in these patients.

### Study objective

This study aims to show that CT colonography is feasible in combination with 4-phase CT of the liver in one session, has good diagnostic accuracy and is associated with fewer complications and is therefore the investigation of

choice in these patients.

## Study design

Fifty consecutive patients with end stage liver failure due to undergo screening prior to being placed on the waiting list for liver transplant at the department of Gastroenterology and Hepatology, Leiden University Medical Center and who fulfil the following criteria and who consent to the study will be investigated with CTC and 4-phase CT of the liver on the same day.

## Study burden and risks

Bowel preparation necessary for the CT colonography  
Limited extra radiation exposure due to scanning the whole abdomen and not just the liver.

## Contacts

### Public

Leids Universitair Medisch Centrum

Postbus 9600  
2300 RC Leiden  
NL

### Scientific

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Postbus 9600  
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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

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

## Inclusion criteria

Endstage liver failure  
Eligible for a liver transplant

## Exclusion criteria

Under 18 years of age  
Inflammatory bowel disease  
Previous colorectal adenomatous polyps or cancer  
Primary Sclerosing Cholangitis

## Study design

### Design

**Study type:** Observational invasive  
**Masking:** Open (masking not used)  
**Control:** Uncontrolled  
**Primary purpose:** Diagnostic

### Recruitment

NL  
**Recruitment status:** Recruitment stopped  
**Start date (anticipated):** 01-07-2011  
**Enrollment:** 50  
**Type:** Actual

## Ethics review

Approved WMO  
**Date:** 23-08-2010  
**Application type:** First submission

## 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	NL27023.058.10