Colonoscopy in liver transplants (LT): prevalence and risk of advanced adenomas post-LT

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The primary objective of this study is to evaluate the prevalence and risk of advanced colorectal neoplasia in asymptomatic non-PSC post-liver transplant recipients compared to an age- and sex matched general population.Secondary Objectives- To...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON34470

Source
ToetsingOnline

Brief title
Prevalence advanced adenomas post-LT

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
advanced adenomen, Colorectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: advanced adenoma, colonoscopy, liver transplant, risk

Outcome measures

Primary outcome

Primary endpoint is defined as the prevalence and risk of advanced colorectal neoplasia detected by a post-LT colonoscopy program compared to the asymptomatic general population.

Secondary outcome

- For patients with pre-transplant colonoscopy protocol, the prevalence of advanced colorectal neoplasia at surveillance colonoscopy will be determined and compared to the general population where a surveillance procedure has been performed. As comparison, the results from the project *Surveillance after polypectomy*- Towards efficient guidelines* from the Department of Public Health of the Erasmus MC University Medical Centre will be used. This study is now in process in the Erasmus MC in 2006 (File number 80-00702-98-088). Furthermore, studies from the literature will be used that evaluate yield of surveillance colonoscopy stratified for baseline colonoscopy findings.
- For patients without pre-transplant colonoscopy work-up, the prevalence of advanced colorectal neoplasia will be determined and compared to non-LT cohorts for advanced neoplasia in asymptomatic individuals reported in the literature.
- Difference in prevalence and risk (Risk Difference [RD]) of advanced neoplasia between post-LT patients with pre-LT colonoscopy and patients without pre-LT colonoscopy.
- To evaluate the differences between locations of neoplasia, morphology of

neoplasia and age of post-LT patients compared to non-LTx cohorts reported in

the literature.

Study description

Background summary

Liver transplantation (LT) is being performed in an increasing number of patients nowadays. It is the most effective treatment for multiple end stage liver diseases with excellent results in short and midterm outcomes. However, concerning long term outcome several malignancies have been observed. Whether there is an increased risk for colorectal cancer in LT recipients is controversial. Some studies have shown an increased risk for CRC and colonoscopy surveillance has been advised. However, others could not confirm this increased risk. A markedly increased risk for CRC is established in primary sclerosing cholangitis (PSC) patients, both in patients with and without LT. For PSC patients, surveillance guidelines for colorectal neoplasia are recommended in terms of annual surveillance colonoscopy. However, the need for adjustment in surveillance guidelines concerning CRC in the non-PSC post-liver transplantation setting is not yet clear. Additionally, the value of pre-transplant colonoscopy screening is still not clarified due to underreporting of the pre-transplant screening work-up in published studies. This may result in differences in yield of colonic adenomas in the post-transplant setting.

Study objective

The primary objective of this study is to evaluate the prevalence and risk of advanced colorectal neoplasia in asymptomatic non-PSC post-liver transplant recipients compared to an age- and sex matched general population.

Secondary Objectives
- To evaluate the observed prevalence and risk of advanced neoplasia found by a colonoscopy in asymptomatic non-PSC post liver transplant recipients with pre-transplant colonoscopy screening compared to the age and sex matched general population.
- To evaluate the observed prevalence and risk of advanced neoplasia found by a colonoscopy in asymptomatic non-PSC post liver transplant recipients without pre-transplant colonoscopy protocol compared to the age- and sex matched general population.
- To evaluate the difference in prevalence and risk of advanced colorectal neoplasia 5 years post-LT in asymptomatic non-PSC post-liver transplant

recipients with pre-transplant colonoscopy compared to asymptomatic non-PSC post-liver transplant recipients without pre-transplant screening colonoscopy.

Study design

Prospective observational intervention study in a multi-center setting

Study burden and risks

A colonoscopy will be performed and include bowel preparation, burden of the colonoscopy in terms of discomfort and complication risks (0.3%), but possible risk reduction for CRC. Most common complications that may occur in colonoscopy procedures are perforation and bleeding as well as cardiopulmonary events such as depressions.

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

Group A: Post liver transplant patients without pre-LT colonoscopy
Patients who
- Have a follow-up of at least 5 years after receiving their first LT.
- Have had orthotopic liver transplantation (OLT).
- Have had non-PSC transplant indications;Group B
• B1 Post liver transplant patients with pre-LT colonoscopy negative findings:
Patients who
- Have a follow-up of at least 5 years after receiving their first LTx
- Have had orthotopic liver transplantation (OLT)
- Are Non-PSC transplant indications
Colonoscopy results within 5 years of post-LT follow-up in post-LTx patients will also be included in the analyses
Patients with a post-LTx colonoscopy before 5 years of post-LTx follow-up who are still alive at time at inception, will also be asked to participate in the post liver transplant colonoscopy program (>= 5 year FU)

B2 Post liver transplant patients with pre-LTx colonoscopy positive findings:
Patients who
- Have a follow-up of at least 5 years post-LT
- Have had orthotopic liver transplantation (OLT)
- Have had non-PSC transplant indications
If patients have 3 or more adenomas at pre-LT colonoscopy (which require intensified surveillance work-up in the Dutch polypectomy guideline10), the follow-up colonoscopy results within 3 years of follow-up after the index colonoscopy in post-LTx patients will be included in the analyses. If patients did not receive their appropriate 3-year surveillance colonoscopy, they will be asked for inclusion.

Exclusion criteria

Patients who:
- have had an other bowel screening procedure pre-LT such as barium enema and/or sigmoidoscopy)
- are unable or not willing to give informed consent
- do have coagulopathy (prothrombin time < 50% of control; partial thromboplastin time > 50 seconds) or patients who have anticoagulants (marcoumar or sintrom) that can not be stopped
- are under 18 years of age
- have had auxiliary LTx
- have PSC
- are known with IBD (UC or Crohn*s disease)
- have undergone a total colectomy

- do not have a post-LTx follow-up colonoscopy and are dead at time of inception

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2011
Enrollment:	350
Type:	Actual

Ethics review

Approved WMO Date:	29-10-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-12-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-05-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL32961.078.10