Non-Invasive rapid assessment of patients with liver transplants using Magnetic Resonance Imaging with LiverMultiScan

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Primary objective- To investigate whether the introduction of LiverMultiScan as a standardised diagnostic test for liver disease can match the diagnostic yield of existing biopsies.Secondary objective- To determine patient feedback from this...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational invasive

Summary

ID

NL-OMON45260

Source
ToetsingOnline

Brief title
RADIcAL 2 study

Condition

- Hepatic and hepatobiliary disorders

Synonym
de novo or recurrent graft rejection of post-transplanted liver - liver failure

Research involving
Human

Sponsors and support

Primary sponsor: Perspectum Diagnostics

Source(s) of monetary or material Support: Europese unie - Horizon 2020 subsidie

Intervention

Keyword: Liver, Liver biopsy, Multiparametric quantitative MRI, Transplantation

Outcome measures

Primary outcome

The liver iron, liver fat, cardiovascular function and the Liver Inflammation

Fibrosis scores (LIF) compared to biopsy results for iron, fat,

fibroinflammatory status and rejection

Secondary outcome

- Patient feedback from qualitative research

- Concordance between MR measurements of fibrosis/rejection and

elastography/blood tests

- Comparison of LIF with clinical diagnosis using blood tests and liver

histology

Study description

Background summary

Long-term survival after solid organ transplantation has increased during the last decades due to improvements in surgical technique, peri-operative care, and more efficient immunosuppression (IS). However, transplant recipients still exhibit higher morbidity and mortality than the general population. One of the main causes are co- morbidities negatively influenced by chronic IS drug usage. It is, however, a very fine balance, as under-usage of IS can lead to transplant rejection. Therefore, many paediatric and some adult liver transplant recipients have regular liver biopsies as part of their serial evaluation, so-called *routine liver biopsies*. Biopsy is performed if there is suspected rejection, as no current non-invasive tests are both sensitive and specific for rejection. However, liver biopsy carries a risk of complication (1 in 10,000), they are painful, sample only a tiny fraction of the liver and for

children there is a need to sedate. Therefore they are less than perfect for serial evaluation.Identification of a reproducible and reliable non-invasive assessment tool for the transplanted liver, such as multiparametric quantitative MRI, would therefore substantially benefit the liver transplant population.We would like to see if the implementation of LiverMultiScan to monitor the transplant population and modify treatment can replace or equal the yield of invasive liver biopsies in the post-transplant population.

Study objective

Primary objective
- To investigate whether the introduction of LiverMultiScan as a standardised diagnostic test for liver disease can match the diagnostic yield of existing biopsies.

Secondary objective
- To determine patient feedback from this population (transplant recipients) on LiverMultiScan.
- To assess how multiparametric MRI correlates with other measures of fibrosis and rejection (eg elastography, blood tests) in the evaluation of these patients.
- To evaluate the utility of LMS in the diagnosis of de novo or recurrent liver disease post-transplant

Study design

This will be a prospective, multi-centre, biomarker trial comparing the accuracy of a new test (LiverMultiScan) against an existing test (Routine liver biopsy) in the assessment of liver transplant recipients, designed in accordance with the STARD criteria. Additional permission will be asked to donate blood for the biobank for further research.

Study burden and risks

There are no anticipated risks associated with this study. The patients will not recieve any direct benefit from participation. There is no gurantee or promise that patients will recieve any benefits from this study.

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

- Patient over 18 years old with a liver transplant.
- Patient due to undergo routine liver biopsy or biopsy for suspected pathology after liver transplantation

Exclusion criteria

- Any contraindication to magnetic resonance imaging (inc pregnancy, pacemaker, shrapnel injury, severe claustrophobia).
- Any contraindication to liver biopsy (coagulopathy, obstructed biliary tract with high risk bile leak, ascites etc)
- Patients who are unable to tolerate MRI without sedation or general anaesthetic

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):	05-12-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	12-07-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL60644.058.17

Study results

Date completed: 10-02-2021

Actual enrolment: 56

Summary results
Trial is onging in other countries