Non-invasive rapid assessment of non-alcoholic fatty liver disease (NAFLD) using Magnetic Resonance Imaging with LiverMultiScan (RADIcAL)

Published: 11-07-2017
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Primary objective: To investigate whether the introduction of LiverMultiScan as a standardised diagnostic test for liver disease can prove a cost effective method in different EU territories.Secondary Objectives:- To investigate patient satisfaction...

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

Summary

ID

NL-OMON50322

Source
ToetsingOnline

Brief title
RADIcAL 1 study

Condition

- Hepatic and hepatobiliary disorders
- Metabolism disorders NEC

Synonym
fatty liver, Non-alcoholic fatty liver disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Diagnosis, Liver, Multiparametric quantitative MRI, NAFLD

Outcome measures

Primary outcome

Primary outcome *proportion of patients with suspected NAFLD incurring liver

related hospital consultations and/or liver biopsies

Secondary outcome

- Patient feedback from qualitative research using a questionnaire

- Clinical outcome measures will be metrics reported by the scan * liver iron,

liver fat, cardiovasculaire status and the Liver Inflammation Fibrosis score

(cT1 value) * compared to histology and /or non invasive test results in

patients in the control arm

- Certainty of diagnosis is defined as a binary (yes/no vs. unlikely/probable)

and frequency as (yes/probable vs. no/unlikely)

- Time from randomisation to diagnosis by the physician.

- Rates of consultations, investigations, admissions

- Cost-effectiveness of LiverMultiScan based on randomised comparison

- Personnel required to perform procedures and tasks

Study description

Background summary

Non-alcoholic fatty liver disease (NAFLD) is a spectrum of disease from fatty liver to non-alcoholic steatohepatitis, fibrosis, and cirrhosis. At the last advanced end of the spectrum, non-alcoholic fatty liver (NAFL) is an excess of fat in the liver (steatosis) present in 20-30% of the general population and is largely asymptomatic. In around 5-6% of patients with NAFL only the condition progresses to non-alcoholic steatohepatitis (NASH), fibrosis, or cirrhosis. In this small group there is a risk of death from liver failure or hepatocellular carcinoma, or needing a liver transplant. The number of hospital admissions for liver damage at the more severe end of the NAFLD spectrum, fibrosis and cirrhosis, are increasing every year.

Study objective

Primary objective:
To investigate whether the introduction of LiverMultiScan as a standardised diagnostic test for liver disease can prove a cost effective method in different EU territories.

Secondary Objectives:
- To investigate patient satisfaction with LiverMultiScan instead of existing care (with other liver investigations)
- To confirm the correlations between LiverMultiScan and liver biopsy results using AUC, PPV and NPV
- To investigate certainty and frequency of diagnosis at points of time in the patient pathway.
- To investigate which pathway was quicker to get to the diagnosis as recorded at final follow-up visit? (including all corrections and additional investigations).
- To measure what healthcare was used in the two diagnostic pathways and subsequent follow-up
- To investigate skills/specialisation required

Study design

This will be a multicentre phase 4 randomised controlled trial to determine the implementation and health care cost of LiverMultiScan versus routine methodical assessment of NAFLD (control arm) in different EU territories. Randomisation is essential in that it will minimise clinician biases over referral practises.
Each patient referred to be evaluated for suspected fatty liver disease will be randomised to either a current management arm, as per local guidelines and choices, or to a second arm, where patient assessment begins with a LiverMultiScan requested by the hepatologist in charge of the NAFLD programme at each centre. Patients will attend for one dedicated study visit after which they will be followed up for a minimum of 12 months, either when they attend for routine clinic appointments, or by telephone, post, email, and/or personal visit. Additional permission will be asked to donate blood for biobanking. For

the final assessment liver function test and NAS score have to be checked by GP or appropriate clinician.

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

* Male and female patients aged 18-75, due to undergo evaluation for suspected

non-alcoholic fatty liver disease
* Participant is willing and able to give informed consent for participation in the study.
* Within standard of care presence of:
- elevated liver function tests (ALT, AST or GGT * 1.5 x upper limit of normal and ALT, AST * 5 x upper limit of normal) up to 1 year prior to patient recruitment
OR
- imaging suggestive of Fatty liver disease up to 3 years prior to patient recruitment OR
Presence of * 3 of the following criteria at screening::
1) insulin resistance or type 2 diabetes mellitus
2) obesity (BMI > 30 or waist-to-hip ratio > 1.00 for men / > 0.85 for women)
3) hypertension (* 130/85 mmHg)
4) elevated triglycerides (* 1.7 mmol/l)
5) low HDL-cholesterol (< 1.05 mmol/l for men / < 1.25 mmol/l for women)

Exclusion criteria

* The participant may not enter the study if they have any contraindication to magnetic resonance imaging (inc pregnancy, extensive tattoos, pacemaker, shrapnel injury, severe claustrophobia).
* Patients with proven liver disease other than NAFLD.
* Liver transplantation
* Patients that present with clinical signs of chronic liver failure (variceal bleeding, ascites, overt encephalopathy)
* Pregnancy
* Alcohol over-use/ abuse as determined by local guidelines
* Patient with known malignant liver tumours and those with any malignancy with life expectancy < 36 months
* Heart failure NYHA stages II-IV

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-09-2017
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	11-07-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	19-10-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	10-03-2020
Application type:	Amendment
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	NL60844.058.17

Study results

Date completed: 31-12-2020

Actual enrolment: 177

Summary results
Trial is onging in other countries