Liver function stress test - Chocolate stress test

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22865

Source Nationaal Trial Register

Brief title Chocolate stress test

Health condition

Quantitative assessment of liver function, Mebrofenin uptake, Hepatobiliary scintigraphy,

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Amsterdam Source(s) of monetary or material Support: Academic Medical Center (AMC), Amsterdam

Intervention

Outcome measures

Primary outcome

Change in total liver function after ingestion of the challenge agent in comparison with the initial liver function, expressed as absolute value (%/min/m2) and percentage of initial liver function.

Secondary outcome

Difference in initial total liver function between younger and elderly subjects (%/min/m2).

Difference in change of total liver function after ingestion of the challenge agent between younger and elderly subjects (%/min/m2).

Study description

Background summary

Surgical resection remains the only curative treatment for primary or secondary liver tumors. Preoperative evaluation of the future remnant liver (FRL) is important in the assessment of patients undergoing major liver resection. Liver resection performed in absence of a sufficient FRL can lead to post-hepatectomy liver failure, a severe life-threatening complication.

99mTc-mebrofenin hepatobiliary scintigraphy (HBS) is a quantitative liver function test and is used to assess total liver function (TLF) in patients scheduled for major liver resection

Normally, HBS is performed after a 4 hours fast. The hepatocytes are presumably in a resting state which might reflect the resting liver function. It is presumable that the liver has a reserve capacity during stimulation. Knowledge of the stimulated liver function could be of interest for optimal patient selection, especially patients with borderline FRL function, since TLF might be underestimated in fasting patients.

We aim to explore changes in the TLF, expressed in mebrofenin uptake rate (%/min/m2) after stimulation with a fatty food challenge prior to HBS.

Study objective

We expect to demonstrate an increase in total liver function after stimulation with a fatty food challenge in comparison with fasting state; liver functional reserve capacity.

We expect younger individuals to differ in total liver function and functional reserve capacity compared to the elderly (\geq 75 years)

Study design

12 patients between 50-60 years old

12 patients \geq 75 years old

We hope to have included all 24 patients before the end of 2017

Intervention

Subjects will undergo HBS twice during 2 visits. For the second HBS-scan, 250 mL full fat chocolate milk will be administered to the participating subjects 30 minutes prior to the scan.

Contacts

Public

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Eligibility criteria

Inclusion criteria

Age between 50-60 or \geq 75 years

No known hepatic disease No previous hepatic procedures No previous chemotherapy treatment No known allergies/intolerance for the administered challenge agent (full fat chocolate milk) Signed informed consent obtained prior to any study-specific procedures

Exclusion criteria

Age < 50 or between 61-74 years Known with hepatic disease Underwent hepatic procedures in the past Treated with chemotherapy in the past Allergies/intolerance for the challenge agent (full fat chocolate milk) Pregnancy or breastfeeding Not able to sign informed consent.

Study design

Design

Study type:InterventionalIntervention model:ParallelAllocation:Non controlled trialMasking:Open (masking not used)Control:N/A , unknown

Recruitment

NL Recruitment status:

Recruiting

Start date (anticipated):	27-01-2015
Enrollment:	24
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	04-07-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43977 Bron: ToetsingOnline Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6271
NTR-old	NTR6613
ССМО	NL51764.018.14
OMON	NL-OMON43977

Study results