FunctiOnal lIver MicrocIrculation measured by SorbiTol and Indocyaninegreen plasma Clearance, the OptIMISTIC- study.

Published: 06-07-2012
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Objectives: The objective of the study is to observe the sorbitol clearance and compare this to ICG clearance in different circumstances of normal and compromised liver blood flow.

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38110

Source
ToetsingOnline

Brief title
Functional liver microcirculation, the OptIMISTIC-study

Condition

- Other condition
- Hepatic and hepatobiliary disorders

Synonym
Liver failure (liver transplant patients); hemihepatectomy for cancer; sepsis.

Health condition

sepsis

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: D-sorbitol, functional blood flow, indocyanine green, liver

Outcome measures

Primary outcome

Primary study objectives;

The main study objective is the clinical use of D-sorbitol plasma clearance as

a measure of functional liver blood flow.

Secondary outcome

Not applicable.

Study description

Background summary

Summary: D-sorbitol is a polyol, a sugar-alcohol. It has been used as an artificial sweetener in the food industry, and was used in the past as an intravenous fluid, for instance in total parenteral feeding solutions. It is metabolised in the liver through the fructose pathway. The rate of metabolism is dependant on the speed with which the substance is transported to the hepatocytes and thus dependant on blood flow through the liver. Therefore, the plasma disappearance rate of D-sorbitol can be used as a measure of blood circulation through, and function of the liver. This method has been used in the past in patients with liver failure based on cirrhosis. Only sporadically has D-sorbitol plasma clearance been used in the ICU, and only in patients with cirrhosis.
Apart from general factors such as liver enzymes and clotting factors, the plasma clearance of several substances has been used as a measure of function of, or blood circulation through the liver. The ideal substance is non-toxic, inert, is exclusively extracted from the circulation by the liver and has a

high extraction ratio, i.e. the substance is rapidly cleared by the liver. The 'gold standard' is the plasma disappearance rate of indocyanine green (ICG). D-sorbitol is a substance with a high liver extraction ratio (0.96), and the plasma clearance is almost completely liver dependant, apart from a smaller, easy to measure and much lower renal clearance. The target of this research project is to establish the clinical use of D-sorbitol in the ICU and a comparison with ICG.

Study objective

Objectives: The objective of the study is to observe the sorbitol clearance and compare this to ICG clearance in different circumstances of normal and compromised liver blood flow.

Study design

Study design: The study will be carried out in the Operation Department and the Department of Intensive Care of the Erasmus University Medical Center (B. van der Hoven, MD and dr. D. Gommers, MD PhD) and is designed as a single-center observational study.

Intervention

Injection of two different substances and measuring plasma clearance to evaluate the functional liver blood flow in all groups of patients.

Study burden and risks

Risk assessment: The measurements pose no additional risks to the patient. The methods used are based on data from extensive earlier research in patients with and without disturbed liver function and our own animal model research.

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

• Inclusion criteria:;o Age 18 years or older.;o Informed consent of the test person or from her/his lawful representative.;o Patients admitted for liver transplant, hemi-hepatectomy for primary or secondary liver malignancy, or sepsis. ;The control group will be recruited from patients admitted for subarachnoid bleeding without liver disease.

Exclusion criteria

• Exclusion criteria:;o No informed consent.;o Allergy for the administered substances, including inborn errors of the *fructose-pathway*.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	48
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	D-sorbitol 5% (2R,3R,4R,5S)-hexaan-1,2,3,4,5,6-hexaol)
Generic name:	D-sorbitol 5% (2R,3R,4R,5S)-hexaan-1,2,3,4,5,6-hexaol)
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	ICG-PULSION 25 mg
Generic name:	Indocyaninegreen
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	06-07-2012
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Not approved

Date:	26-07-2012
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EudraCT	EUCTRNL32291.078.12-NL
CCMO	NL32291.000.12