Liver function Hepatobiliary Scintigraphy Scintigraphy (HBS) in combination with Selective Internal Radiation Therapy (SIRT)

Published: 25-11-2013
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The objective of the study is to assess the additional value of monitoring segmental liver function with HBS in patients undergoing SIRT.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON45011

Source
ToetsingOnline

Brief title
HBS with SIRT

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
liver cancer; liver metastases

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Hepatobiliary Scintigraphy Scintigraphy, liver cancer, liver function, Selective Internal Radiation Therapy

Outcome measures

Primary outcome

The primary endpoint of this study is defined as segmental liver function in

treated and untreated lobes expressed as absolute value (%/min/m2) and

percentage of total liver function 6 weeks after SIRT; and changes in total

liver function after SIRT.

Secondary outcome

Secondary endpoint is the correlation of scintigraphic findings with clinical

and biochemical parameters such as performance score, Chil-Pugh-Turcotte score

and serologic liver function tests collected as part of the routine patient

management.

Study description

Background summary

Selective internal radiation therapy (SIRT) is a form of brachytherapy in which intra-arterially injected (90)Y-loaded microspheres serve as sources for internal radiation purposes of liver tumors. Average disease control range from 70% up to 90% or even higher and SIRT is usually very well tolerated. Most complications are mild and can be prevented by careful patient selection. Severe complications result from the excessive irradiation of non-target liver tissue. This can lead to radioembolization induced liver disease (REILD), a potentially life threatening complication. Furthermore, SIRT will result in a (temporary) decreased liver function due to the irradiation of the non-target liver tissue.

It could be beneficial to perform SIRT in two sessions enabling the primary untreated liver segments to guarantee liver function until function in the

treated segments has recovered. Though, changes in the liver function after SIRT have not been described before.

Currently, HBS is the only liver function test able to measure both the total and regional liver function. For liver surgery, HBS has been validated as a tool to assess liver function and is performed routinely in patients before major liver resection in the AMC. It is also used to assess segmental liver function before and after portal vein embolization in patients with insufficient future remnant liver.

Therefore, we consider HBS a valuable quantitative liver function test enabling assessment of changes in the liver function after SIRT.

Study objective

The objective of the study is to assess the additional value of monitoring segmental liver function with HBS in patients undergoing SIRT.

Study design

The study is designed as a prospective, single arm, observational cohort study in 20 patients.

Study burden and risks

An increase in radiation exposure is involved with the additional HBS-SPECT. Radiation burden for this procedure is 13.6 mSv for both scans. . The additional radiation burden is >10mSv which is considered a moderate risk category for adults. Tough, patients will be also treated with high dose SIRT because of an unresectable tumor in the liver. Furthermore, the life expectancy in this patient group is limited and the risk of suffering long term consequences due to the additional radiation caused by SPECT-CT is small. In this light the additional amount of radiation exposure can be seen as justifiable.

Furthermore patients need to fast during minimal 4 hours before the procedure, though patients who undergo HBS prior to liver resection or because of PVE experience little discomfort as a consequence of the fasting. Moreover, patients will be injected with 200 MBq 99mTc-mebrofenin intravenously. Though, HBS is a safe procedure with no procedure related complication

Furthermore, the burden for subjects consists of two visits to the hospital to perform two HBS scans.

The blood drawings and all the biochemical parameters that will be measured are

already part of standard SIRT protocol.

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

Patients with hepatocellular carcinoma or liver metastases of other primary who are referred for SIRT.
Age * 18 years.
Signed informed consent obtained prior to any study-specific procedure.

Exclusion criteria

Age * 18 years.
Pregnancy or breastfeeding.

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):	22-01-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	25-11-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL44984.018.13