Long-term follow-up of patients with extrahepatic biliary atresie and Kasai hepatoportoenterostomy: assessment of abnormalities on MR imaging and implications for follow-up.

Published: 16-01-2007
Last updated: 14-05-2024

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

Summary

ID

NL-OMON30396

Source
ToetsingOnline

Brief title
MR imaging after Kasai portoenterostomy

Condition

- Hepatic and hepatobiliary disorders

Synonym
congenital biliary atresia; Kasai portoenterostomy

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: biliary atresia, Kasai portoenterostomy, liver, MR imaging

Outcome measures

Primary outcome

The final purpose of our study is to formulate guidelines for follow-up imaging

examinations in this patient group.

Secondary outcome

not applicable

Study description

Background summary

Extrahepatic biliary atresia is the most important cause of neonatal cholestasis, in which the extrahepatic bile ducts are obstructed. The treatment consists of hepatoportoenterostomy according to Kasai, in which a bile loop is connected to the porta hepatis. Virtually all patients eventually develop cirrhosis, due to longstanding chronic cholestasis. We hypothesize that these patients are at increased risk for development of hepatocellular carcinoma.

Between 1977-1986 in Holland, 71 children underwent a hepatoenterostomy according to Kasai. In a recent study which was performed in Utrecht Medical Center, a retrospective analysis was done to determine the survivors of this group; the children that had undergone liver transplantation; and which patients had died. Of the 16 patients that still have their native liver, currently, it is unknown if there are cirrhotic features, the extend of cirrhosis and the status of the liver metabolism.

Study objective

In the present study, this cohort of patients will be examined once by means of MR imaging. We expect to be able to determine if, and how frequently, these

patients will have to examined by means of follow-up MR imaging in the future. The final purpose of our study is to formulate guidelines for follow-up imaging examinations in this patient group.

Study design

The included patients will be examined once by means of MR imaging, which will be performed in the Erasmus MC. This examination will be performed according to the currently used *liver - hepatocellular carcinoma* protocol. Total scantime is approximately 45 minutes. On the next visit to the outpatient clinic, a minor clinical examination will be performed, aiming at recording the size of both liver and spleen, determining the presence of icteric features, spider naevi and/or ascites. In addition, the relevant blood serum values will be determined (which is routinely determined once yearly regardless). The results of these analyses will be sent to the researchers after permission of the participant. The MR examinations will be assessed by two radiologists.

Study burden and risks

The patients will be examined once by means of MR imaging.

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 that underwent Kasai portoenterostmy > 10 years ago for extrahepatic biliary atresia
. patients did not undergo livertransplantation
. signed informed consent

Exclusion criteria

- severe cardiovascular or pulmonary condition
- pregnancy or lactation
- cardiac pacemaker, or presence of any other metal objects within the body
- metal workers
- severe claustrophobic complaints

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2007
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO Date:	16-01-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL15014.078.06