Pregnancy And Liver adenoma Management

Published: 26-08-2011
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In this study we will investigate the management of HCA during pregnancy based on a prospectively acquired online database in the Netherlands.

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

Summary

ID

NL-OMON47417

Source
ToetsingOnline

Brief title
PALM-study

Condition

- Hepatic and hepatobiliary disorders

Synonym
liver adenoma

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,Stichting Coolsingel

Intervention

Keyword: Liver adenoma, Management, Pregnancy

Outcome measures

Primary outcome

*To investigate the proportion of patients in which HCA growth during pregnancy occurs

Secondary outcome

*To investigate in which trimester of pregnancy growth of HCA occurs;

*To investigate the degree of growth of HCA during pregnancy;

*To investigate whether there is regression of HCA postpartum;

*To investigate the HCA-related interventions during pregnancy;

*To investigate the incidence of bleeding of HCA during pregnancy;

*To investigate liver-related clinical signs during pregnancy;

*To investigate elevated liver enzymes during pregnancy;

*To evaluate the quality of life of pregnant patients with HCA;

*To investigate whether there is a difference between quality of life of pregnant patients with HCA and pregnant patients with other comorbidity that have an indication for pregnancy care at the obstetrician in secondary care and healthy pregnant patients.

Study description

Background summary

Hepatocellular adenoma (HCA) in pregnant women requires special considerations because of the risk of hormone induced growth and spontaneous rupture, due to increased levels of steroid hormones during pregnancy that may threaten the life of both mother and child. Most experts advocate that women with HCA should not get pregnant or advise surgical resection before pregnancy. We recently proposed not to discourage all women with HCA from pregnancy, based on a study

in which we monitored twelve women with documented HCA during a total of 17 pregnancies. In 4 cases HCA*s grew during pregnancy, requiring a Caesarean section in 1 patient (2 pregnancies) and radiofrequency ablation in 1 case during the first trimester of pregnancy. All pregnancies had an uneventful course with a successful maternal and fetal outcome. However, there is no evidence-based algorithm for the evaluation and management of HCA during pregnancy, due to scarcity of cases. The conclusion not to discourage all women with HCA from pregnancy has, however, to be proven in a large multicentre study in which we will closely monitor pregnant patient with a HCA in a prospectively acquired database to give more insight in the behaviour of HCA during pregnancy.

Study objective

In this study we will investigate the management of HCA during pregnancy based on a prospectively acquired online database in the Netherlands.

Study design

In this study we will investigate the management of HCA during pregnancy based on a prospectively acquired online database in the Netherlands. The PALM-study is a multi-centre prospective case-control study.

Study group
Properly Dutch speaking, pregnant patients, 18 years of age or older with a radiologically (MRI with liver specific contrast agent) and/or histologically proven diagnosis of HCA can be included in the study. Radiological diagnosis of HCA will be based on contrast enhanced magnetic resonance imaging (pre- or postpartum). Lesions must not exceed 5 cm. These patients have an indication for pregnancy care at obstetrician in secondary care.

In the first weeks of pregnancy patients will be referred to the obstetrician for pregnancy care. Baseline starts at 14 (+/- 3) weeks of gestation. At this day and every 6 weeks patients will undergo ultrasound (US) of the HCA lesion at the hepatologist and patients will, if possible, undergo a venapunction at 14 and 32 weeks of pregnancy. Before US of the HCA lesions and 2 days afterwards patients will be asked to fill out the Shortform 36 (SF-36) questionnaire.

Study burden and risks

Patients will experience minimal impact of this study, without additional risks. The study takes time from the patient.

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

Study groep: Properly Dutch speaking, pregnant patients, 18 years of age or older with a radiologically and/or histologically proven diagnosis of hepatocellular adenoma can be included in the study. Radiological diagnosis of HCA will be based on contrast enhanced magnetic resonance imaging (pre- or postpartum). Lesions must not exceed 5 cm. Informed consent must be signed.

Exclusion criteria

Dementia or impaired mental function that would counter the understanding of giving informed consent.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2011
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	26-08-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-04-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-11-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-03-2018
Application type:	Amendment

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	NL36058.078.11