Elastographical and Ultrasonic Properties of the Liver and Hepatic Circulation during severe preeclampsia/HELLP Syndrome

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The aim of this study is to test the hypothesis that severe pre-eclampsia/HELLP syndrome in comparison to patients without severe preeclampsia/HELLP are accompanied by changes in hepatic circulation and themselves cause changes in elastographic...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Maternal complications of labour and delivery
Study type	Observational non invasive

Summary

ID

NL-OMON31441

Source
ToetsingOnline

Brief title
Liver and Hepatic Circulation in severe preeclampsia/HELLP Syndrome

Condition

- Maternal complications of labour and delivery

Synonym
Pregnancy Toxicosis and HELLP syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Circulation, Elasticity, HELLP syndrome, Liver

Outcome measures

Primary outcome

To determine differences in flow characteristics of the hepatic circulation and

liver elasticity in women with a normal pregnancy versus women with severe

preeclapmsia/ HELLP-syndrome

Secondary outcome

not applicable

Study description

Background summary

Severe preeclampsia/HELLP-syndrome is a severe complication of pregnancy, which occurs during the second and third trimester. The syndrome has significant morbidity and mortality of mother and child. It is characterized by arterial hypertension, hemolysis and elevated liver enzymes and can be complicated by hematoma and rupture of the liver in rare cases.
During a normal pregnancy, physiological and functional changes of the liver occur, but
little is known about hepatic blood flow. In 1947 Munnell and Taylor1 published the first study on hepatic vessels during pregnancy in which hepatic vein catheterization was performed in pregnant women. In 15 patients with normal pregnancies the hepatic blood flow was not different from nonpregnant women. In a much later period, 2002, a second study with Doppler ultrasound of the hepatic vessels was performed. In 67 healthy pregnant women and 22 nonpregnant women the total liver blood flow was increased during the third trimester, in which the major determinant seemed to be the portal venous return2.
In the study of Roobottom et al.3 and Pekindel et al.4 loss of pulsatility in venous Doppler waveforms was demonstrated, also implicating changes in the hepatic perfusion.
A few conducted studies specifically investigating alterations in the hepatic artery and portal vein in severe preeclampsia/HELLP-syndrome demonstrated

varying and contradictive results. Oosterhof et al.5 demonstrated excessive and abnormal constriction of the hepatic artery, whereas Kurzel et al.6 could not demonstrate a significant difference. The latter study only was conducted in the postpartum period.
Kawabata et al.7 studied the predictive value of dual hepatic flow in patients with severe preeclapmsia/HELLP syndrome. In patients with severe preeclampsia/HELLP the dual hepatic blood supply was lowered significantly.
In women with severe preeclampsia/HELLP syndrome in which liver pathology has been examined focal necrosis in the liver parenchyma, edema and also focal thrombosis occurs. The etiology is not known.
In order to test our hypothesis that the elastographical properties change during severe preeclampsia/HELLP syndrome due to thrombosis, inflammation and edema we performed a pilot study in 17 patients with severe preeclampsia and the HELLP syndrome in which there appeared to be a significant difference in elastographical properties, which resolve very quickly after delivery. To this date there are no investigations on elastographical properties in pregnant women.
In order to test our second hypothesis that alterations in blood flow cause damage to the liver parenchyma through ischemia and constriction of the hepatic artery we want to investigate the hepatic perfusion by abdominal ultrasound combined with Doppler measurements.
During this examination the following investigations will be performed:
- aspect liver parenchyma (steatosis, signs of bleedings/edema)
- aspect of the biliary tract (dilation, stones and sludge)
- hepatic veins (diameter, flow pattern and flow velocity)
- portal vein (diameter, flow pattern and flow velocity)
- hepatic artery (flow pattern, flow velocity, resistance index)
- the presence or absence of ascites
- length and width of the spleen
- Inferior vena cava (diameter, flowpattern, flow velocity)

Also, when an arterial or deep venous line is present blood will be drawn during the investigation. This to determine the severity of the syndrome during the examination which might change.
Laboratory testing includes:
- Bloodcount
- Liverenzymes with bilirubin
- Albumine, uric acid and haptoglobin
- Renal function tests (kreatinin and urea)
- Glucose
- Prothtombine time

Study objective

The aim of this study is to test the hypothesis that severe pre-eclampsia/HELLP syndrome in comparison to patients without severe preeclampsia/HELLP are accompanied by changes in hepatic circulation and themselves cause changes in

elastographic properties of hepatic tissue due to edema, thrombosis and inflammation.

Study design

All patients admitted to the high care and obstetrical ward in the Sophia Children*s Hospital and the ICU in the Erasmus Medical Centre in Rotterdam with severe pre-eclampsia and the HELLP-syndrome are asked to participate.
After written informed consent abdominal Doppler ultrasound in combination with elastography (by FibroScan) will be performed by two physicians. Before this investigation the patients will be asked to answer questions concerning previous liver diseases, other diseases, use of medication, smoking and/or alcohol and family history (see CRF-form).
Abdominal ultrasound investigation takes approximately 20 minutes, whereas transient elastography takes approximately 10 minutes.
Total examination time including abdominal ultrasound, measuring elasticity and answering of the questions takes 45 minutes.
When an arterial or deep venous line is present blood will be drawn, otherwise blood is taken during regular testing moments while admitted.
During admission additional elastographical measurements with the FibroScan will be taken on day 3 and 5, and when necessary at day 7. This will take approximately 10 minutes. There are no requirements necessary before taking the measurements, also there will be no additional testing via blood or questions.
Next to these patients, women with a healthy pregnancy visiting the outpatient clinic with a matching gestational age will be asked to participate as a healthy control. In addition, a CRF-form will be requested to answer and abdominal Doppler ultrasound and elastography will be performed.

Study burden and risks

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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

Age > 18 years
Severe preeclampsia/HELLP syndrome

Exclusion criteria

Age < 18 years
Inability to perform ultrasound or elastographical measurements of the liver

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2009
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	05-01-2009
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	NL18909.078.08