

Congenital Cytomegaly Virus Infection: correlation of Fetal MRI findings vs clinical outcome

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28326

Source

NTR

Brief title

CMV

Health condition

Congenital CMV infection

Sponsors and support

Primary sponsor: N/A

Source(s) of monetary or material Support: Fetal Medicine Foundation Belgium

Intervention

Outcome measures

Primary outcome

Diagnostic accuracy of in utero MRI in case of congenital CMV

Secondary outcome

Study description

Background summary

The aim of the study is to improve the prenatal counselling of parents and to guide future management decisions in cases of proven cCMV infection. In particular the emphasis is on the additional contribution made by in utero MRI relative to the information already established by antenatal ultrasound, timing of CMV infection. In order to achieve this, the following measures will be analysed:

- Comparison of the diagnostic agreement between antenatal ultrasound and in utero MRI
- Quantification of the diagnostic accuracy of MRI in cases of proven cCMV infection (with reference to clinical and pathological outcome)
- Correlation of MRI findings with clinical outcome.
- Comparison between the first MRI diagnosis at the first center and the second look by a trained fetal MRI specialist.

Study objective

Fetal MRI can be helpfull in detecting CMV related lesions and can help in this way the counseling of patients in the future.

Study design

1 MRI during pregnancy
at least 1 clinical follow up postnataland/or autopsy findings.

Intervention

second look fetal MRI + correlation postnatal follow up

Contacts

Public

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Eligibility criteria

Inclusion criteria

- CMV seroconversion during pregnancy
- CMV positive amniotic fluid or/and CMV positive urine neonate.

Exclusion criteria

- No signs of CMV in amniotic fluid or/and positive urine neonate.
- no postnatale follow up.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-06-2013
Enrollment:	250
Type:	Unknown

Ethics review

Positive opinion	
Date:	06-09-2013
Application type:	First submission

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
NTR-new	NL3990
NTR-old	NTR4162
Other	: Mieke Cannie
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A