Urinary NTproBNP to reduce eye examinations in preterm infants

Published: 04-07-2012
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To confirm the previously reported negative predictive value of urine NTproBNP for ROP in large, multi center cohort of preterm infants.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON39687

Source
ToetsingOnline

Brief title
REDEXAM study

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
Retinopathy of prematurity; Retina injury after preterm birth

Research involving
Human

Sponsors and support

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

Intervention

Keyword: NTproBNP, retinopathy of prematurity

Outcome measures

Primary outcome

100% negative predictive cut-off values for urinary NTproBNP concentrations normalized to creatinine at 2 and 4 weeks of life for threshold ROP (stage II+ or more in zone 2 or 3, or any ROP in zone 1)

Secondary outcome

100% negative predictive cut-off values for urinary NTproBNP concentrations normalized to creatinine at 2 and 4 weeks of life for ROP intervention (laser-/cryo surgery)

100% negative predictive cut-off values for urinary NTproBNP concentrations at 2 and 4 weeks of life without normalization to creatinine for threshold ROP (stage II+ or more in zone 2 or 3, or any ROP in zone 1)

100% negative predictive cut-off values for urinary NTproBNP concentrations at 2 and 4 weeks of life without normalization to creatinine for ROP intervention (laser/cryo surgery)

Study description

Background summary

Preterm infants with a gestational age < 30 weeks and a birth weight < 1500 g have an increased risk of retinopathy of prematurity (ROP). For this reason the eyes of these infants are screened every 2 weeks by the ophthalmologist, a procedure that can be uncomfortable and painful. In the end, only 10% of the infants have ROP that needs treatment. A recent study showed that NTproBNP measured in urine spots a 2 and 4 weeks of age, has a excellent negative predicting value for ROP. Using NTproBNP might significantly reduce the need for eye exams in preterm infants.

Study objective

To confirm the previously reported negative predictive value of urine NTproBNP for ROP in large, multi center cohort of preterm infants.

Study design

In this observational study NTproBNP will be determined in urine spots at 2 and 4 weeks of age. Care of the preterm infants will be according to the local protocol and the NTproBNP results will have no impact on treatment or eye screening. By combining the results from the eye exams and the NTproBNP, diagnostic value of the later will be determined.

Study burden and risks

This is an observational study in which infants will receive care as usual. Urine will be collected at 2 and 4 weeks via a small plastic bag or a cotton wool. Based on this design there is no anticipated burden or risk for the patients participating in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Gestational age < 30 weeks and birth weight < 1500 gram

Exclusion criteria

- Lack of parental consent
- infant likely to die soon
- infant scheduled for early transfer to another institution without reliable ophthalmologic examinations (not applicable to the Netherlands)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-11-2012
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	04-07-2012
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	NL40854.018.12