

HIPPO study - Happiness for Improvement of Premature and Parental Outcome

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To determine stress and comfort exposure at the NICU for both neonates and their parents in a cohort of preterm born neonates, to relate this to short- and long-term morbidity, and to epigenetic changes during neonatal life.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22163

Bron

Nationaal Trial Register

Verkorte titel

HIPPO

Aandoening

preterm birth

Ondersteuning

Primaire sponsor: Erasmus Medical Center

Overige ondersteuning: Vriendenloterij

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Main study parameter is the exposure to stress and level of comfort during the NICU admission for both the parents and the infant. Next to this, residual body material will be collected to analyse biochemical and epigenetic changes in the neonate during neonatal life. Data regarding stress and comfort during the prenatal, perinatal and neonatal period will be related to short- and long-term outcome obtained by the national standard of care follow-up program

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Preterm birth and the admission to a Neonatal Intensive Care Unit (NICU) is stressful for neonates and their parents. The degree of stress and pain after preterm birth during intensive care treatment is wide-ranging, but previous studies indicate that it has detrimental and long-lasting effects. While these previous studies often used one type of quantification for the cumulative level of stress and the outcome of the neonate, we believe that a more extensive approach is necessary to better understand the role of stress and comfort during pregnancy, birth, NICU admission and beyond for both children and their parents.

Objective: To determine stress and comfort exposure at the NICU for both neonates and their parents in a cohort of preterm born neonates, to relate this to short- and long-term morbidity, and to epigenetic changes during neonatal life.

Study design: This is a national multicenter observational cohort study in which preterm neonates and their parents will be followed prospectively during neonatal life; from birth until the 28th day of life, or before day 28 in case of discharge from the NICU afore.

Study population: Premature neonates born with a gestational age of less than 29 weeks admitted to a NICU in the Netherlands within a 12 months inclusion period.

Intervention: This is a non-intervention observational cohort study. Data regarding stress and comfort will be collected using the medical record and weekly questionnaires for parents.

Moreover residual body material (cord blood, urine, meconium, redundant breastmilk and neonatal residual blood) will be collected where possible. Furthermore, a small piece of hair of the parents will be collected 6 weeks after birth. Parents and nurses will be asked to daily rate the level of stress and happiness for the infant.

Main study parameters/endpoints: Main study parameter is the exposure to stress and level of comfort during the NICU admission for both the parents and the infant. Next to this, residual body material will be collected to analyse biochemical and epigenetic changes in the neonate during neonatal life. Data regarding stress and comfort during the prenatal, perinatal and neonatal period will be related to short- and long-term outcome obtained by the national standard of care follow-up program.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The risk of participation in this study is negligible. No additional examinations will be performed for this study and no extra blood will be drawn from the participants.

We aim for a 'stress-free study' for the neonate, the parents and the caregivers. Therefore, this study aims to cause no stress related burden. We will only use residual body material

and ask minimal time and effort from parents and caregivers to fill out questionnaires. We would like to ask a minimum amount of time from the parents to make participation in this study as easy as possible.

All data will be anonymised using specific study codes as identifiers and permission will be asked from the parents. This study can only be performed within this population because of the specific circumstances and developmental stage of the (premature) neonates.

Doel van het onderzoek

To determine stress and comfort exposure at the NICU for both neonates and their parents in a cohort of preterm born neonates, to relate this to short- and long-term morbidity, and to epigenetic changes during neonatal life.

Onderzoeksopzet

Focus on first 28th days of life

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

Erasmus MC - Sophia
Sinno Simons

0031641376695

Wetenschappelijk

Erasmus MC - Sophia
Sinno Simons

0031641376695

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Gestational age below 29 0/7 weeks
- Signed agreement of participation and use of data from both parents or guardians

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Because the questionnaires for parents will only be available in Dutch and English, parents that insufficiently understand these languages to fill in the questionnaires will be excluded from this part of the study. However, if they are able to read the patient information folder (in Dutch or English) they will not be excluded from the data collection regarding their child and the collection of biomaterial for both the infant and his/her parents.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	14-07-2020
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
to be decided

Ethische beoordeling

Positief advies

Datum: 02-10-2020

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8939
Ander register	METC Erasmus MC : MEC-2019-0574

Resultaten

Samenvatting resultaten

no publications yet available