HIPPO study - Happiness for Improvement of Premature and Parental Outcome

No registrations found.

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

Summary

ID

NL-OMON22163

Source
Nationaal Trial Register

Brief title
HIPPO

Health condition

preterm birth

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Vriendenloterij

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Long term follow-up (tbd)

Study description

Background summary

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.

Study 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

Focus on first 28th days of life

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

- Gestational age below 29 0/7 weeks

- Signed agreement of participation and use of data from both parents or guardians

Exclusion criteria

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.

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:	Recruiting
Start date (anticipated):	14-07-2020
Enrollment:	400
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
to be decided

Ethics review

Positive opinion

Date:	02-10-2020
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	NL8939
Other	METC Erasmus MC : MEC-2019-0574

Study results

Summary results
no publications yet available