Family Integrated Care in the Neonatal Ward - the AMICA study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26390

Source
Nationaal Trial Register

Brief title
AMICA

Health condition

Prematurity

Sponsors and support

Primary sponsor: OLVG, JB van Goudoever (Emma Children's Hospital)
Source(s) of monetary or material Support: Stichting OLVG

Intervention

Outcome measures

Primary outcome

Neurodevelopment

Secondary outcome

Breastfeeding, length of stay, sepsis, cortisol, bloodpressure, growth, IVH, ROP, BPD.

Parental: stress, parent-infant bonding, postnatal depression, self-efficacy, empowerment, postnatal PTSD, cortisol

Study description

Background summary

Approximately 7% of the children are born preterm and have to be admitted to the Neonatal department. The AMICA study is a medical-scientific study on the influences of a (prolonged) hospitalisation during the postpartum period on infant and parents. This is often a very stressful
and emotional period for the parents and the child. Sometimes parents and their child are separated and this might pose extra stress. Some children are admitted in the hospital for up to 4 months. We study how parent participation during hospital stay can influence health outcomes of infants and their parents in the short- and longterm.

Study objective

Family Integrated Care in Single Family Rooms improves neurodevelopmental outcome in preterm infants

Study design

during hospital stay, discharge, and 1,3,6,12,18 and 24 months of corrected age.

Intervention

Single Family Rooms with Family Integrated Care

Contacts

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Eligibility criteria

Inclusion criteria

Hospitalised children:
- Born between 24 and 36 6/7 weeks gestational age, with a postconceptional age < 44 weeks on admission
- At least 1 week of hospital stay on the Neonatal Ward
- Will visit the Outpatient Clinic of the OLVG East, OLVG West or NWZA after discharge or consents to gather required information through infant health centers
- Written informed consent from the parents

Healthy controls:
Born at term (37 to 41 weeks of gestational age)
- Spontaneous vaginal birth without hospitalisation post-partum
- Written informed consent from the parents

Exclusion criteria

Metabolic or chromosomal/syndromal diseases
- Therapeutic hypothermia for perinatal asphyxia
- Severe psychiatric or psychosocial problems i.e. parents under supervision of youth care
- Transfer to another hospital before discharge
- Parents are unable to answer the questionnaires in Dutch/English
- Death of an infant

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-05-2017
Enrollment:	600
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	23-12-2016
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	NL6175
NTR-old	NTR6322

Register	ID
Other	NLABR / MEC-U : 56691

Study results