fAMily Integrated CAre in the neonatal ward - the AMICA-study

Published: 22-12-2016
Last updated: 17-04-2024

Our primary objectives are: 1. To evaluate the effect of Family Integrated Care in SFR on neurodevelopmental outcome at 2 years of (corrected) age in newborns hospitalized in a level-2 Neonatal Ward for at least 1 week as compared to standard...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal and perinatal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON47775

Source
ToetsingOnline

Brief title
the AMICA-study

Condition

- Neonatal and perinatal conditions
- Adjustment disorders (incl subtypes)
- Family issues

Synonym
Prematurity

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: Nutricia,Stichting OLVG

Intervention

Keyword: Care by parents, Family Integrated Care, Neonatology, Single Family Rooms

Outcome measures

Primary outcome

To evaluate the effect of Family Integrated Care in SFR on neurodevelopmental outcome at 2 years of (corrected) age in newborns hospitalized in a level-2 Neonatal Ward for at least 1 week as compared to standard neonatal care in open bay units as measured by the Ages and Stages Questionnaire 3rd edition.

To evaluate the effect of Family Integrated Care in SFR on parental stress at discharge as compared to standard neonatal care in open bay units as measured by the Parental Stress Scale.

To study and provide norms of parental (traumatic) stress, parent-infant bonding, depression and anxiety and parental self-efficacy over time in the healthy (non-hospitalised) population.

Secondary outcome

To study short-term clinical outcomes of Family Integrated Care in SFR in newborns hospitalized to a level-2 Neonatal Ward for at least 1 week (e.g. breastfeeding rates, growth, sepsis, respiratory support, critical incidents, duration of hospital stay).

Infants will be followed-up after discharge until the age of 2 years to assess breastfeeding rates, growth, iron status, hospital readmission and psychomotor development.

To study the influence of at least 1 week Family Integrated Care in SFR on parental outcome measures like parent-infant bonding, degree of family centred

care, parental self-efficacy, parental satisfaction levels during hospital stay

and after discharge.

To study the effect of Family Integrated care in SFR on longterm cortisol

levels in hair (in infants and in parents).

Study description

Background summary

Due to the technological environment of the modern neonatal ward, premature or sick newborns and their parents are commonly separated worldwide, and both physical and emotional closeness is impaired. The early postnatal life is a sensitive period of development and impairment of mother- infant interactions (such as maternal separation or deprivation) is a threat to this.
Developmental research has firmly established the quality of the relationship between an infant and his or her parent as an important factor influencing the child*s later development. When children develop a secure relationship with their parents or caregivers in their first years of life, they generally have better cognitive outcomes, better social interactions, display less behavioural problems, and achieve better at school.
Parents of ill newborns experience high levels of stress, anxiety and depression. This is of concern since the mental and psychological health of the mother can affect her relationship with her infant and thus the infant*s cognitive and emotional development.
To address the well-known disadvantages of early separation, we have adapted and implemented a Family Integrated Care model for use in a level 2 Neonatal Ward with Single Family Rooms (SFRs) in which parents provide most of the care for their infant, while nurses support, teach and counsel parents.

Study objective

Our primary objectives are:
1. To evaluate the effect of Family Integrated Care in SFR on neurodevelopmental outcome at 2 years of (corrected) age in newborns hospitalized in a level-2 Neonatal Ward for at least 1 week as compared to standard neonatal care in open bay units.
2. To evaluate the effect of Family Integrated Care in SFR on parental stress at discharge as compared to standard neonatal care in open bay units.
3. To study and provide norms of parental (traumatic) stress, parent-infant bonding, depression and anxiety and parental self-efficacy over time in the

healthy (non-hospitalised) population.

Study design

In this prospective observational cohort study we will study infants and parents cared for with Family Integrated Care in Single Family Rooms for at least 1 week compared to infants and parents who were provided with standard neonatal care in open bay units in 2 other hospitals.

Due to the nature of this study, and hospital architectural design, randomisation between hospitals is not possible. Also randomisation within hospitals is not possible, with the possible effect of cross-contamination. Therefore, we have chosen for a prospective observational cohort study with 1 intervention centre, 2 standard care centres and a random selection of control infants visiting the infant health care centres within the area of the hospitals.
Group A (intervention) is treated with Family Integrated Care in SFR and group B (standard care) treated with standard neonatal care in OBU. In OLVG East infants will enter Group A, in OLVG West and NWZA infants will enter Group B. All wards are level 2 Neonatal Wards, with a comparable patient population (see further section 5: table 1). Longitudinally, a communal random sample of infants and their parents at the infant health care centers (GGD) around the participating hospitals will be followed to control for and cross-validate outcomes. The study will not be blinded.

Study burden and risks

Up till now, no study has been performed regarding involvement of parents in care for infants from 30 weeks of postnatal age in a Level 2 Neonatal Ward. If we are able to show that this new concept of care in these groups of vulnerable patients is better than standard care regarding neurodevelopment and parental stress, this concept of care should be considered as a strategy in other neonatal wards.

The only burden for the parents is time-related, for filling out the questionnaires. The total amount of time required to fill out the questionnaires will be 2 times 20-30 minutes during hospital stay and at discharge. And during follow-up parents will be asked to fill out questionnaires 4 times befeore their visit at the outpatient clinic. The burden for the newborns is none since all studied parameters are part of the routine clinical care and are noted in the clinical chart.
Scoring the forms on stress, anxiety, self-efficacy and bonding leaves us with a signaling attitude towards the parents* (mental) health. Parents are usually supported by a child-psychologist during stay in the ward. If the questionnaires are indicative of the necessity of (psychological) help for the parents, than we will notify the parents and will search for appropriate

assistance (ie notify the treating doctor or general practitioner in consultation with the parents).

Additionally, the collection of hair samples is done on the posterior vertex of the head. Approximately 100 hairs will be sampled.

Contacts

Public
Onze Lieve Vrouwe Gasthuis

Oosterpark 9
Amsterdam 1091 AC
NL
Scientific
Onze Lieve Vrouwe Gasthuis

Oosterpark 9
Amsterdam 1091 AC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- Born between 24 and 37 weeks of gestational age
- At least 1 week of hospitalisation
- Will not be transferred to an other hospital before discharge
- Will visit the Outpatient Clinic of the OLVG East, OLVG West and NWZA

(location Alkmaar) after discharge

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 or life-threatening illness of sibling

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-05-2017
Enrollment:	1953
Type:	Actual

Ethics review

Approved WMO

Date:	22-12-2016
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-05-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-09-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-02-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-10-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-10-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-05-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
Other	6175
CCMO	NL56691.100.16