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Improving neonatal outcomes by training nurses in Brazil

Submission date
09/11/2011

Recruitment status
No longer recruiting

Registration date
05/12/2011

Overall study status
Completed

Last Edited
31/10/2019

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Prematurity is defined as a gestation of <37 completed weeks, and low Birth Weight (BW) as <2,500g. Very preterm infants are <32 weeks gestation and Very Low BW (VLBW) <1500g. VLBW babies have much higher mortality rates than full term babies, and prematurity can lead to serious complications with life-long implications. These include Retinopathy of prematurity (ROP), which can lead to irreversible blindness; broncho-pulmonary dysplasia (BPD), a form of chronic lung disease; serious infection and infection of the gut (necrotising enterocolitis) which can cause death or other long term problems. Many VLBW babies also fail to grow and gain weight which adversely affects their development. Mortality rates among VLBW babies vary, ranging from >45% in NICUs in low and middle income countries to less than 10% in industrialized countries. Good organization and management of care are critical factors influencing the outcome of neonatal care, and rigorous adherence to protocols has been shown to improve outcomes in India.

Who can participate?
Premature babies (<1500 gs or <34 weeks gestational age) cared for in neonatal intensive care units in Rio de Janeiro, Brazil.

What does the study involve?
1. An educational package offered to all nurses in each participating neonatal unit
2. Provision of minimal essential equipment e.g. for monitoring oxygen in each unit according to need

The comparison will be before and after delivering the intervention.

What are the possible benefits and risks of participating?
If the intervention improves nursing care, then this will lead to fewer complications and lower mortality. There are no side effects.

Where is the study run from?
Six neonatal units in Rio de Janeiro

When is the study starting and how long is it expected to run for?
From March 2008 to end of 2011

Who is funding the study?
Swiss foundation

Who is the main contact?
Professor Clare Gilbert
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NA

Study information

Scientific Title
Improving neonatal outcomes by training nurses in Brazil: a non-randomised trial

Study objectives
Studies carried out by the applicants in 6 NICUs in Rio since 2004, as well as routine data show that:
1. Mortality among VLBW babies in Rio is 32%
2. Rates of BPD reported by the local neonatology network are 11.3%
3. Sepsis rates in VLBW babies are also very high at > 60%
4. Rates of severe ROP in VLBW babies vary from 3.7 -12.5% being much higher than in industrialized countries
5. Poor nutritional status is common
6. Equipment for monitoring oxygen is often inadequate, or not optimally used
7. Nurses are often unaware of their critical role in reducing mortality and complications

8. The ratio nurses/baby was below the nationally recommended level for Brazil (1 nurse for 2 babies), ranging from 1:2 in only one unit to 1:17 in another

These findings suggest that much can be done at relatively low cost to reduce mortality and the complications of prematurity, by training nurses and increasing equipment for monitoring oxygen saturation levels.

Training nursing staff who care for preamature babies in neonatal units in Brazil and providing additional supervisory support and minimum essential equipment will improve a range of outcomes of neonatal intensive care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the London School of Hygiene and Tropical Medicine approved on 4th September 2007, ref 5195. Amended to allow qualitative research to explore reasons behind the findings: A228/5195, 4th February 2011

Study design
Non-randomised trial with before and after measures

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Preterm babies

Interventions
The intervention was developed with the nursing staff and with the input of local neonatology colleagues, and was an interactive process so that the training materials and approach was the most appropriate for the setting. The interventions consisted of:
1. Six self taught modules covering the following:
1.1. Pain control
1.2. Oxygen control
1.3. Infection control
1.4. Nutrition
1.5. Temperature control
1.6. Supportive care e.g. kangaroo care
2. Each of the six elements were supported by a DVD which demonstrated aspects of the training materials
3. A before and after self assessment, to encourage learning
4. Training and support of two nurse trainers
5. Provision of minimum essential equipment e.g. probes for oximeters. Each unit created a list of equipment which was ordered (Note: The equipments unfortunately did not arrive in time)

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Rates of retinopathy of prematurity defined as ROP severe enough to warrant treatment

Key secondary outcome(s))
1. Mortality rates, by birthweight group
2. Sepsis within 48 hours of birth and after 48 hours
3. Bronchopulmonary dysplasia, defined as requiring oxygen at 28 days after birth and on oxygen at 36 weeks postmenstrual age
4. Necrotising enterocolitis

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Premature babies in seven neonatal intensive care units in Rio de Janeiro Brazil
2. Babies weighing < 1500gs at birth who were inborn in these units

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Birth weight 1,500g or more
2. Major congenital abnormalities

Date of first enrolment
01/01/2007

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
United Kingdom

England

Brazil

Study participating centre
International Centre for Eye Health
London
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Sponsor information

Organisation
London School of Hygiene and Tropical Medicine (UK)

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
Swiss Foundation (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/03/2012	31/10/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes