

Improving neonatal outcomes by training nurses in Brazil

Submission date 09/11/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/12/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 31/10/2019	Condition category Pregnancy and Childbirth	<input type="checkbox"/> 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
clare.gilbert@lshtm.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Clare Gilbert

Contact details
International Centre for Eye Health
Clinical Research Department
London School of Hygiene and Tropical Medicine
Keppel Street
London
United Kingdom
WC1E 7HT
+44 (0)20 7958 8332
clare.gilbert@lshtm.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Rates of retinopathy of prematurity defined as ROP severe enough to warrant treatment

Secondary outcome measures

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

Overall study start date

01/01/2007

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

Age group

Neonate

Sex

Both

Target number of participants

800-900 in the seven units overall; 400-450 in each of the years before and after the POINTS of Care intervention

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**

Brazil

England

United Kingdom

Study participating centre

International Centre for Eye Health

London

United Kingdom

WC1E 7HT

Sponsor information**Organisation**

London School of Hygiene and Tropical Medicine (UK)

Sponsor details

c/o Penny Ireland

Keppel Street

London

England

United Kingdom

WC1E 7HT

+ 44 (0)20 7927 2678

penny.ireland@lshtm.ac.uk

Sponsor type

University/education

Website

<http://www.lshtm.ac.uk>

ROR

<https://ror.org/00a0jsq62>

Funder(s)

Funder type

Government

Funder Name

Swiss Foundation (Switzerland)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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