ISRCTN13554391 https://doi.org/10.1186/ISRCTN13554391

Pulsatile, audible, tactile stimulation for premature babies in neonatal intensive care units to reduce pain and increase weight gain

Submission date	**Recruitment status**	[X] Prospectively registered
10/09/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/09/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/09/2015	Neonatal Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

About 11% of all babies born worldwide are preterm (premature) meaning that they are born more than three weeks before their due date. Premature babies have had less time to develop in the womb, and so often have a low birth weight. These infants also are more likely to have medical problems, which often require extensive medical support to ensure that they survive. Sometimes invasive medical procedures are needed, which can cause pain and stress to the baby. This has been linked to the baby not developing normally, which can cause both the child and parents great difficulties. Tactile stimulation (activating the senses through touch) in the form of massage has been shown to be beneficial for the growth and development of premature babies. This can be difficult to do by hand, as it is time consuming and not always practical when the baby is in an incubator. The pulsatile audible-tactile stimulation (PATS) mattress is a device which can be placed inside an incubator, providing tactile stimulation through gentle, pulsing vibrations. The aim of this study is to find out whether using a PATS mattress can help to lower pain levels and increase weight gain in premature babies.

Who can participate?

Infants born up to 10 weeks early, who weigh more than 1000 grams at the start of the study.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in the first group (intervention group) sleep on a PATS mattress in their incubator for 14 days and then for every other hour for 9 hours each day for the rest of the study period. Those in the second group (control group) sleep on a regular incubator mattress at the same times for the rest of the study period. When the babies have blood tests (normal practice for premature babies), they are filmed. These films are then reviewed by experts to determine each baby's pain levels. The weight of the children is also measured in grams every day through the 14 day study period.

What are the possible benefits and risks of participating?
Benefits of using a PATS mattress are not currently known, but they may help the babies in the intervention group to gain weight and feel less pain. There are no risks of participating in the study.

Where is the study run from?
National Hospital Edgardo Rebagliati (Peru)

When is the study starting and how long is it expected to run for?
November 2014 to December 2016

Who is funding the study?
1. Grand Challenges Canada (Canada)
2. Fondecyt Peru (Peru)

Who is the main contact?
1. Dr Cynthia Anticona (Public)
cynthiaanticona@hotmail.com
2. Dr Monica Pajuelo (Scientific)
mjpajuelo@gmail.com

Contact information

Type(s)
Public

Contact name
Dr Cynthia Anticona

ORCID ID
http://orcid.org/0000-0001-9321-6174

Contact details
Las Secoyas B6
La Molina
Lima
Peru
511
+51 988 855083
cynthiaanticona@hotmail.com

Type(s)
Public

Contact name
Dr Monica Pajuelo

Contact details
Manuel Tovar 340
Miraflores
Lima

Peru
511
+51 994 670488
mjpajuelo@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Pulsatile, audible, tactile stimulation for premature infants in neonatal intensive care units to reduce pain and increase weight gain

Study objectives
Premature infants receiving the pulsatile audible tactile stimulation will show less pain levels and increased weight gain compared to premature infants in a control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the Hospital Edgardo Rebagliati (Peru)

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Prematurity

Interventions
Participants are randomly allocated into one of two groups:

Intervention group: Infants rest on a special incubator mattress called PATS for a period of 14 days. During this period, they will receive the pulsatile audible tactile stimulation (provided by the PATS mattress) for 9 hours per day, every other hour, starting at 6 am and ending at 12 pm (midnight).
The PATS is a low-cost mattress that provides a pulsatile audible-tactile stimulation (PATS). On its top side (the side which is in contact with the newborn), the mattress has a plastic pocket containing a water film. Through this water film, a vibration-producing device inserted in the mattress foam provides the tactile pulsatile stimulation. In addition, two small speakers located on the corners of the mattress will produce a record of sounds similar to the mother's heartbeat. The range of sounds goes from 100 to 300 Hertz, which is the range of intrauterine audible perception. The sounds produced are less than 45 decibels as recommended by the American Academy of Pediatrics. The result is a pulsatile tactile audible stimulus. The stimulus duration is 25 hundredths of a second and the frequency is 60 per minute (similar to the normal heart rate of an adult at rest). The provision of the pulsatile audible tactile stimulation is controlled by an electronic system operated using a 12-volt rechargeable battery.

Control Group: Infants rest on a regular incubator mattress, and will be followed up for 14 days.

Intervention Type
Other

Primary outcome measure
Pain levels will be assessed from videos of each participant receiving venipuncture procedures using the Premature Infant Pain Profile (PIPP) scale, within the first three days of the intervention and then between days 12 and 14.

Secondary outcome measures
Weight gain will be measured daily over the 14 day intervention period at the same time by a NICU nurse using a calibrated neonatal scale.

Overall study start date
01/11/2014

Completion date
20/07/2017

Eligibility

Key inclusion criteria
1. Medically stable
2. Gestational age between 30 and 33 weeks + 6 days
3. Birth weight between 1000 and 1400 grams
4. Weight at the time of recruitment > 1000 grams
5. Parental informed consent

Participant type(s)

Patient

Age group
Neonate

Sex
Both

Target number of participants
120

Key exclusion criteria
1. APGAR score < 7 at 5 minutes.
2. Genetic abnormalities, gastrointestinal and cardiac birth defects, central nervous system birth defects, intrauterine growth retardation.
3. Diseases related to prematurity including: severe hyperbilirubinemia, grade III or IV intraventricular hemorrhage, necrotising enterocolitis, chronic lung disease.
4. Persistent infections or metabolic problems during hospitalization.
5. Maternal history of: alcohol or illicit drugs exposure, syphilis , hepatitis B , HIV and other intrauterine infections .
6. Medical conditions that alter the body movement or the ability to participate in the intervention, pathological fractures, bone deformities or seizures.
7. Outgoing or scheduled surgery within the first 28 days of life.
8. Use of sedatives or painkillers at the onset of the study or in the previous 72 hours.
9. Use of postnatal steroids.

Date of first enrolment
01/02/2016

Date of final enrolment
20/12/2016

Locations

Countries of recruitment
Peru

Study participating centre
Hospital Nacional Edgardo Rebagliati
Jesus Maria
Lima
Peru
150

Sponsor information

Organisation
Sociedad Peruana de Pediatría

Sponsor details
Los Geranios 151 Lince
Lima
Peru
511

Sponsor type
Other

Funder(s)

Funder type
Government

Funder Name
Grand Challenges Canada

Alternative Name(s)
Grands Défis Canada, GCC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
Fondecyt Peru

Results and Publications

Publication and dissemination plan
We plan to publish the study protocol by January 2016. The article with the results of the clinical trial would be published by September 2017.

Intention to publish date
31/01/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration