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The effect of Vimala massage on stress hormone levels in the saliva of premature babies

Submission date
25/03/2022

Recruitment status
No longer recruiting

Registration date
29/03/2022

Overall study status
Completed

Last Edited
28/03/2022

Condition category
Neonatal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In neonatal intensive care units across the world, premature babies are exposed to a very stressful environment with high levels of noise, bright lights, pain, infections, invasive procedures, and a lack of maternal contact. Massage has been reported to be associated with decreased levels of stress, cortisol and with increased oxytocin levels. The aim of this study is to assess the impact of Vimala massage on salivary cortisol levels, clinical signs of stress and growth in premature babies admitted to a neonatal intensive care unit.

Who can participate?
Premature babies (28-36 weeks gestational age) admitted to a nursery unit

What does the study involve?
Participants are randomly allocated to receive 15-20 minutes of Vimala massage administered by their parents twice daily and usual care, or to receive usual care only. Salivary cortisol levels are measured on days 1 and 5. Heart rate, breathing rate, calorie intake, weight gain and growth are recorded daily.

What are the possible benefits and risks of participating?
The possible benefits of participating are lower cortisol levels and stability of clinical signs of stress. The risks of participating are possible discomfort from massage.

Where is the study run from?
High Specialty Medical Unit No 48, Mexican Institute of Social Security (Mexico)

When is the study starting and how long is it expected to run for?
March 2015 to February 2016

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Salivary cortisol in premature neonates treated with Vimala massage: a randomized controlled trial

Study objectives
Vimala massage impacts the salivary cortisol levels, clinical signs of stress and growth in premature neonates admitted to a neonatal intensive care unit

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/08/2015, Local Health Research Committee 1002 (México e Insurgentes Av. León Gto. México. +52 (0)477 7174800 ext 31804; investigaUMAE48@gmail.com), ref: R-2015-1002-29

Study design
Single-center interventional blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Perinatal health

Interventions
After consent, patients are randomized 1:1 to receive usual nursing care plus Vimala massage (intervention) or usual nursing care alone (control). In the intervention group, parents receive a 20-minute individual session with their child, where they are shown the massage techniques to use and given a printed booklet illustrating the different positions and movements. Parents are then asked to demonstrate the massage maneuvers and demonstrate proficiency in at least 80% of the massage components. The massage is performed by the parents under moderate pressure twice a day for 15-20 minutes on five consecutive days, at 12:00 and 18:00 under the supervision of one of the researchers.

A saliva sample is collected 1 hour before the first day of massage and after 5 days of massage, and at equivalent time points in control infants. Samples are collected between 11:00 and 12:00 and newborns must fast for at least 1 hour before sampling. To stimulate saliva production, two drops of 30% glucose solution are placed on the infants' tongue before the sample was obtained. After oral inspection to ensure there is no milk contamination, a plastic Pasteur pipette is placed inside the cheek to collect the sample. The sample is immediately transferred to plastic test tubes and transported to the laboratory where it is stored at -20°C. Cortisol is measured using the DRG Salivary Cortisol by ELISA test (DRG Instruments GmbH, Marburg,

Germany). The test has detection limits of 0.0537 to 8 micrograms per deciliter with an inter-assay variation of 7.47% and an intra-assay variation of 2.65%.

Intervention Type
Behavioural

Primary outcome(s)
Salivary cortisol measured using the DRG Salivary Cortisol by ELISA test (DRG Instruments GmbH, Marburg, Germany) 1 hour before the first day of massage and after 5 days of massage, and at equivalent timepoints in control infants

Key secondary outcome(s))
1. Heart rate, respiratory rate, and oxygen saturation measured with a Choice brand model MMED 600DP vital signs monitor with saturation sensor in the right hand for five consecutive days between 7:00 and 8:00 am
2. Weight measured with a digital scale Se GmbH & Co. Kg model 374 1321009 (Hamburg, Germany) for five consecutive days at 8:00 am
3. Length measured with a non-elastic anthropometric tape, Seca 201® for five consecutive days at 8:00 am

Completion date
28/02/2016

Eligibility

Key inclusion criteria
1. Premature neonates born by caesarean section or vaginal delivery
2. 28-36 weeks of gestational age (Ballard scale)
3. Admitted to the nursery unit
4. Fed by mouth
5. Hemodynamically stable
6. Required no respiratory support
7. Unremarkable physical examination
8. A parent (mother or father) had to be available and willing to provide massage to the neonate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Total final enrolment
72

Key exclusion criteria
Patients with active infections

Date of first enrolment
30/09/2015

Date of final enrolment
30/12/2015

Locations

Countries of recruitment
Mexico

Study participating centre
Neonatal unit of the Gynecology and Pediatric Hospital Number 48 of the Mexican Institute of Social Security
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Sponsor information

Organisation
Gynecology and Pediatric Hospital Number 48 of the Mexican Institute of Social Security

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes