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Does sleeping position affect the amount of change in heart rate in newborn babies?

Submission date
08/03/2020

Recruitment status
No longer recruiting

Registration date
13/03/2020

Overall study status
Completed

Last Edited
23/10/2020

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Heart rate variability reflects the responsiveness of the autonomic nervous system to environmental factors. In a stressful environment, the sympathetic nervous system dominates, reducing the heart rate variability. Lower heart rate variability is a risk factor for unfavorable outcomes of various diseases, a longer recovery, and sudden heart death in newborns. The aim of this study is to determine whether a newborn's sleeping position affects their heart rate variability.

Who can participate?
Healthy newborns aged 1 to 28 days after birth

What does the study involve?
While the newborns sleep, the researchers measure heart rate variability in four sleeping positions, namely supine without and with tilt, and prone with and without tilt. At the same time they measure blood oxygen levels, heart and breathing rates, blood pressure and body temperature, and assess alertness.

What are the possible benefits and risks of participating?
The benefit of participating is the analysis of the newborn's heart rhythm. If there are heart rhythm problems the researchers consult a pediatric cardiologist. There are no risks of participating.

Where is the study run from?
University Medical Centre Ljubljana (Slovenia)

When is the study starting and how long is it expected to run for?
September 2016 to September 2018

Who is funding the study?
University Medical Centre Ljubljana (Slovenia)

Who is the main contact?
Prof. Matjaž Klemenc
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2020-000701-88

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The effect of sleeping position on heart rate variability in newborns

Study objectives
It is hypothesized that the parameters of heart rate variability might be more favorable for outcome in the supine position compared to prone, even more so with tilt.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/09/2016, National Ethics Committee of Slovenia (Štefanova ulica 5, 1000 Ljubljana, Slovenia; +386 (0)1 478 60 01; gp.mz@gov.si), ref: 0120-458/2016-3 KME 67/09/16

Study design
Cross-sectional cohort study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet (klemenc.matjaz@gmail.com)

Health condition(s) or problem(s) studied
Cardiovascular and respiratory stable newborns who had no respiratory and/or haemodynamic support

Interventions
After feeding, sleeping newborns were placed in a supine position with a 30˚head-up tilt of the bed for 30 min. ECG signals were recorded in four positions: the supine without and with tilt and prone with and without tilt by using an ECG Holter system (Vision 5L, Burdick, USA). Parameters were recorded in every position for at least 30 minutes, when the newborn was sleeping quietly. Simultaneously, the newborn’s alertness was assessed using a five-stage description. In all positions, the breathing frequency (BF) was counted (by visualizing the excursions of the thorax) and heart rate (HR) and blood oxygenation were measured by pulse oximeter (Intelli Vue MP 50, Philips, Germany) 10 min after changing the lying position of the newborn. Blood pressure (systolic and diastolic) was measured noninvasively using an inflatable cuff. Body temperature was measured by infrared non-contact frontal thermometer Veratemp + (Veratemp; USA).

Intervention Type
Behavioural

Primary outcome measure
Heart rate variability (HRV) measured by pulse oximeter for at least 30 minutes when the newborn was sleeping quietly in four positions

Secondary outcome measures
Parameters recorded in every position for at least 30 minutes, when the newborn was sleeping quietly:

1. Blood oxygenation measured using a pulse oximeter
2. Breathing frequency (BF) counted by visualizing the excursions of the thorax
3. Mean arterial blood pressure (MAP) measured using an inflatable cuff

Overall study start date
01/09/2016

Completion date
01/09/2018

Eligibility

Key inclusion criteria
1. Stable cardiovascular and respiratory systems
2. No respiratory and/or hemodynamic support

Participant type(s)
Healthy volunteer

Age group
Neonate

Sex
Both

Target number of participants
50

Total final enrolment
46

Key exclusion criteria
1. Hypoxic ischemic encephalopathy (HIE)
2. Preterm birth
3. Infection
4. Neurological or congenital abnormalities

Date of first enrolment
17/11/2017

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
Slovenia

Study participating centre
University Medical Centre Ljubljana
Neonatal Department of the Division of Paediatrics
Bohoričeva ulica 20
Ljubljana
Slovenia
1000

Sponsor information

Organisation
Ljubljana University Medical Centre

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.kclj.si/

ROR
https://ror.org/01nr6fy72

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Centre Ljubljana

Results and Publications

Publication and dissemination plan

Results expected to be published in BMC Pediatrics.

Intention to publish date
10/09/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Matjaž Klemenc (klemenc.matjaz@gmail.com). Raw data (ECG recordings) will become available from 01/05/2020 for the next 5 years. Access criteria: research in the field of heart rate variability in neonates, statistical analyses, data are anonymised, no ethical or legal restrictions.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/04/2020	23/10/2020	Yes	No