

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

Submission date 08/03/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/03/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/10/2020	Condition category Circulatory System	<input type="checkbox"/> 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
matjaz.klemenc@bolnisenica-go.si

Contact information

Type(s)
Scientific

Contact name
Prof Matjaž Klemenc

ORCID ID
<https://orcid.org/0000-0001-7255-7201>

Contact details
Klementa Juga 16
Solkan
Slovenia
5250
+38 (0)653301141
matjaz.klemenc@bolnisenica-go.si

Additional identifiers

Clinical Trials Information System (CTIS)
2020-000701-88

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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

ROR

<https://ror.org/01nr6fy72>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Medical Centre Ljubljana

Results and Publications

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