Skin condition assessment during routine monitoring versus during wearing of the BAMBI BELT; a wireless device measuring neonatal heart rate, ECG and respiration

Published: 21-05-2021
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To compare skin condition for monitoring with the Bambi Belt versus skin condition with routine monitoring.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal and perinatal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON51115

Source
ToetsingOnline

Brief title
Skin condition and neonatal monitoring

Condition

- Neonatal and perinatal conditions
- Epidermal and dermal conditions

Synonym
prematurity, skin damage

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum

Source(s) of monetary or material Support: Bambi Medical B.V.,Bambi Medical B.V. betaalt de benodigde materialen en een bijdrage voor de tijdsbesteding

Intervention

Keyword: Monitoring, Neonatal, Skin condition, Wireless

Outcome measures

Primary outcome

Skin condition as defined by Trans epidermal water loss

Secondary outcome

Visual inspection of the skin using the Neonatal Skin Condition Score (NSCS)

and adverse event-reporting (if any)

Study description

Background summary

In sick or prematurely born neonates, cardiorespiratory monitoring is routinely performed using adhesive electrodes. Especially in neonatal intensive care units (NICUs), where all infants require monitoring, alternative monitoring methods are desired to replace such skin unfriendly adhesive electrodes, attached to hindering wires.

Study objective

To compare skin condition for monitoring with the Bambi Belt versus skin condition with routine monitoring.

Study design

Prospective observational within-subject study in Máxima Medical Center. Subjects will be allocated to a study ID and wear the Bambi belt (a part of the Bambi Belt System) for 10 consecutive days, in addition to standard monitoring with adhesive electrodes.

Study burden and risks

Non-invasive, observational study in which infants have to wear an additional

monitoring device. Although unexpected, the risk of skin irritation due to this device cannot be ruled out. There are no benefits for participating infants. This study might demonstrate substantial benefits for a similar population in the near future. These potential benefits outweigh the minimal risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

* Being admitted to the NICU
* Being routinely monitored with adhesive electrodes
* Having written parental informed consent
* Being of a post-menstrual age (PMA) cohort that is not already fully represented in the study (to include representative numbers, inclusion is performed in three cohorts (< 28 weeks PMA, between 28-37 weeks, and >37 weeks

PMA))

Exclusion criteria

* Chest skin lesions preventing placement of electrode belt, since the intended use of the belt is for intact skin.
* Congenital anomalies that prevent placement of the belt.
* Effects of surgery preventing or hindering belt placement, such as laparotomy or stoma
* Contraindications of the Bambi Belt, i.e. use during MRI and electrosurgery

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-07-2021
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Bambi belt system
Registration:	No

Ethics review

Approved WMO

Date:	21-05-2021

Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL77561.015.21