Wireless wearable belt for neonatal monitoring

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28282

Source
NTR

Brief title
TBA

Health condition

Prematurity

Sponsors and support

Primary sponsor: Máxima Medical Center
Source(s) of monetary or material Support: Bambi Medical B.V.

Intervention

Outcome measures

Primary outcome

Transepidermal water loss

Secondary outcome

Neonatal skin condition score

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. In this study, the skin friendliness of one such alternatives is compared to skin friendliness of routine monitoring with adhesive electrodes.

Study objective

A wearable, non-adhesive wireless belt is skin friendlier compared to routine adhesive electrodes meant for cardiorespiratory monitoring in neonates.

Study design

Study duration is 10 days. Primary and secondary outcome measures are determined daily.

Intervention

Wearing of wearable belt for 10 days

Contacts

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Eligibility criteria

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) that is not already fully represented in the study (representative numbers of three cohorts are included, < 28 weeks PMA, between 28-37 weeks PMA, > 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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	16-06-2021
Enrollment:	15
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL9478
Other	METC MMC : W21.043

Study results