DIAphragmatic MONitoring of respiratory Diseases using a Sensor

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The objective of this study is to determine the ability of respiratory EMG measurements with a wearable to correlate respiratoryimprovement or deterioration in hospitalised children with respiratory disease.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory tract infections
Study type	Observational non invasive

Summary

ID

NL-OMON56943

Source
ToetsingOnline

Brief title
DIAMONDS

Condition

- Respiratory tract infections

Synonym
Asthma, bronchiolitis, pneumonia

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: EUROSTARS subsidie (no. 2645)

Intervention

Keyword: Asthma, Bronchiolitis, EMG, Pneumonia

Outcome measures

Primary outcome

The main study endpoint is the correlation between changes in diaphragmatic EMG

parameters during hospitalisation and

changes in treatment, i.e. step-up or step-down in treatment.

Secondary outcome

Correlation between diaphragmatic EMG parameters during hospitalization and

parameters that could indicate respiratory distress:

• Respiratory rate

• SpO2

• Heart rate

Study description

Background summary

Monitoring of patients on pediatric wards is currently performed by intermittent observations by nurses and/or doctors. However, a child*s respiratory condition might deteriorate quickly and abruptly. It is difficult to predict clinical deterioration, even for the most skilled and experienced health care providers. On the other hand, clinical improvement during admission for respiratory disease will also be assessed during intermittent observations. Typically, children will only be discharged when respiratory support is stopped and a clinically stable condition has been observed for some time, including a period of sleep to observe vital parameters (e.g. oxygen saturation). Predicting clinical recovery could assist healthcare providers to decide whether discharge from hospital is safely possible, without unnecessarily prolonged admission. Electromyography (EMG) is used as an experimental tool to measure

the activity of the diaphragm in pediatric patients with respiratory disease. It could provide an easy, passive method to monitor respiration in the hospital.

Study objective

The objective of this study is to determine the ability of respiratory EMG measurements with a wearable to correlate respiratory improvement or deterioration in hospitalised children with respiratory disease.

Study design

The study will have an exploratory design.
An adhesive patch will be applied to measure respiratory EMG. This measurement will be performed during the admittance of the subject to the pediatric ward, alongside and not interfering with regular care.

Study burden and risks

The study provides no risks to subjects. The measurements will be performed alongside regular care according to current guidelines. There is no additional burden involved in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Children (2-11 years)
Babies and toddlers (28 days-23 months)
Newborns

Inclusion criteria

• Admitted to pediatric ward of one of the participating hospitals
• Aged 0 till 15
• One of the following (working) diagnoses at admission:
o Asthma
o Bronchiolitis
o BHR or viral wheeze
o Pneumonia

Exclusion criteria

• Admittance to the ICU
• Patient has ICD/pacemaker
• Parents and/or patient cannot understand Dutch
• Informed consent from both parents (if applicable) cannot be obtained
• Skin where patch is positioned is damaged (e.g.. eczema)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-11-2024
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	DIAMONDS sensor
Registration:	No

Ethics review

Approved WMO Date:	08-08-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL87160.091.24