"Electrical impedance tomography and respiratory inductive plethysmography in premature infants on non-invasive respiratory support"

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal respiratory disorders
Study type	Observational non invasive

Summary

ID

NL-OMON37481

Source
ToetsingOnline

Brief title
EIT and RIP in non-invasive respiratory support

Condition

- Neonatal respiratory disorders

Synonym
premature birth, respiratory failure

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Chiesi Farmaceutici,industrie

Intervention

Keyword: electrical impedance tomography, non-invasive support, prematurity, respiratory inductance plethysmography

Outcome measures

Primary outcome

The effects of apnea/coffeine and dopram treatment/surfactant

administration/positional changes on functional residual volume, tidal volume

and ventilation distribution.

Secondary outcome

During the study, all patients will be monitored according to clinical protcol.

Of the available parameters, the following will be registered: heart rate,

breathing frequency, transcutaneous oxygen and carbondioxide tension, current

non-invasive respiratory support pressure and fractional oxygen concentration

(FiO2). Furthermore, patient caracteristics will be obtained like gestational

age, birth weight, age and diagnosis.

Study description

Background summary

Respiratory failure is relatively common in premature infants, mostly caused by apnea of prematurity and respiratory distress syndrome (RDS). Regular treatment comprises of non-invasive respiratory support, combined with position changes and - where needed - additional caffeine/dopram (apnea) and/or surfactant (RDS). The latter is currently administered through an endotracheal catheter during spontaneous breathing. Although this intervention is known to effect lung volume, it is unclear whether this effect is homogeneous. Insight in distribution of lung volume and ventilation is of importance since (regional) collapse and overdistension have been demonstrated to be major risk factors in

development of secundary lung damage. Until recently, bedside tools lacked for registration of (regional) changes in lung volume and ventilation. However, two non-invasive techniques have been developed for monitoring these changes: electrical impedance tomography (EIT) and respiratory inductance plethysmography (RIP).

Study objective

The primary objective is to obtain insight in regional differences in lung volume and ventilation distribution during apnea of prematurity and its farmacological treatment. Furthermore, the effect on these parameters due to position changes and non-invasive administration of surfactant will be studied.

Study design

An observational study of regular treatment.

Study burden and risks

The study comprises of observations of daily regular treatment and hence is of no extra strain to the patient. Both monitoring techniques have been proven to be safe and have been frequently used in research at our department.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

non-invasive respiratory support
premature infants below 34 weeks of gestational age
written informed consent

Exclusion criteria

congenital anomalies of the thorax

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):	27-09-2012
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	14-05-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL39939.018.12