# Continuous Regional Analysis Device for neonate Lung (CRADL)

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To design and test an EIT device and interface for infants based on a modified adult device (Continuous Regional Analysis Device for neonate Lung (CRADL) project). More specifically this protocol focusses on collecting EIT recordings in infants...

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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-OMON46059

**Source**
ToetsingOnline

**Brief title**
CRADL

### Condition

- Neonatal respiratory disorders

**Synonym**
respiratory failure

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** H2020

## Intervention

**Keyword:** electrical impedance tomography, infants, lung aeration, Ventilation distribution

## Outcome measures

### Primary outcome

Distribution of tidal ventilation before and after an intervention or event

that is know for its changes in regional lung aeration and the regional changes

in the right vs the left lung and the anterior vs the posterior part of the

lung.

### Secondary outcome

The relationship and timing of EIT changes compared with onset of

intervention/event or the results from other diagnostic tools will be explored.

# Study description

### Background summary

Both the primary disease state and the effect of clinical interventions can cause heterogeneous lung disease in neonatal and pediatric intensive care patients. This heterogeneity can compromise lung function and lead to long lasting pulmonary morbidity. There are currently no bedside imaging tools to monitor changes in (regional) lung aeration mainly expressed as distribution of tidal ventilation. Electrical Impedance Tomography (EIT) is a promising non-invasive, radiation-free, bedside applicable, monitoring tool for measuring regional changes in lung aeration. EIT has been extensively studied in infants, showing that EIT is feasible and safe in this vulnerable population. However, clinical implementation has been hampered by the lack of an easy to use patient interface, real-time display of EIT recordings, and clinically relevant EIT measures. In the adult population these shortcomings hev been solved and EIT has now entered the clinical arena.

### Study objective

To design and test an EIT device and interface for infants based on a modified adult device (Continuous Regional Analysis Device for neonate Lung (CRADL)

project). More specifically this protocol focusses on collecting EIT recordings in infants needing respiratory support for (imminent) respiratory failure in the intensive care unit.

### Study design

This is an observational study

### Study burden and risks

The results of this study will have no direct benefit to the patient because it is purely observational and the EIT recordings are not available for guiding care. EIT has been used in hundreds of (preterm) infants and is considered a safe and non-invasive monitoring technique. The risk and burden for the patient are therefore considered negligible. This study needs to be conducted in infants because this is the target group for the new EIT device. In adults, the EIT device is already available and implemented in daily clinical care.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

# Eligibility criteria

**Age**
Children (2-11 years)

## Inclusion criteria

Age less than 7 years (limited by available electrode belt sizes)
Admitted to the NICU or the PICU
At high risk of or developing respiratory failure for which respiratory support is needed
Written informed consent from both parents or legal representatives

## Exclusion criteria

Postmenstrual age < 25 weeks
Birth weight < 600 g
Electrical active implant
Chest skin lesions preventing placement of electrode belt

# Study design

## Design

**Study type:** Observational non invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 30-11-2016 |
| Enrollment: | 125 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 25-08-2016 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 28-11-2017 |
| Application type: | Amendment |
| 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 | NL58171.018.16 |