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# Respiratory system mechanics and electrical impedance tomography measurements during mechanical ventilation with heliox in infants with respiratory syncytial virus lower respiratory tract disease

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| **Submission date**<br>20/12/2005 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>20/12/2005 | **Overall study status**<br>Completed | |
| **Last Edited**<br>26/08/2021 | **Condition category**<br>Respiratory | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
NL198 (NTR235)

# Study information

### Scientific Title
Respiratory system mechanics and electrical impedance tomography measurements during mechanical ventilation with heliox in infants with respiratory syncytial virus lower respiratory tract disease

### Study objectives
1. First, mechanical ventilation with a gas mixture composed of helium and oxygen is only beneficial in patients with obstructive Respiratory Syncytial Virus Lower Respiratory Tract Disease (RSV LRTD). Hence correct identification of the clinical phenotype is necessitated. This can be done with lung function testing, including compliance and resistance.
2. Second, the beneficial effect of heliox can be detected with repeated Electrical Impedance Tomography (EIT) measurements.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethics approval received from the local medical ethics committee

### Study design
Randomised, active controlled, crossover group trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Respiratory Syncytial Virus Lower Respiratory Tract Disease (RSV LRTD)

### Interventions

Mechanical ventilation with heliox.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
Respiratory system mechanics (compliance and resistance).

### Secondary outcome measures
Arterial partial pressure of Carbon Dioxide (pCO2).

### Overall study start date
01/10/2005

### Completion date
01/04/2007

## Eligibility

### Key inclusion criteria
Mechanically ventilated infants younger than 12 months of age with a virologically proven RSV infection.

### Participant type(s)
Patient

### Age group
Neonate

### Sex
Not Specified

### Target number of participants
15

### Total final enrolment
13

### Key exclusion criteria
Older than 12 months of age, no informed consent, prior use of corticosteroids, infants on high-frequency oscillatory ventilation and infant wit a haemodynamically significant congenital heart defect.

### Date of first enrolment
01/10/2005

### Date of final enrolment

01/04/2007

# Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**VU Medical Centre**
Amsterdam
Netherlands
1007 MB

# Sponsor information

**Organisation**
VU University Medical Center (The Netherlands)

**Sponsor details**
Van der Boechorststraat 7
Amsterdam
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1081 BT

**Sponsor type**
University/education

**ROR**
https://ror.org/00q6h8f30

# Funder(s)

**Funder type**
Not defined

**Funder Name**
Not provided at time of registration

# Results and Publications

## Publication and dissemination plan
Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary
Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 15/05/2009 | 26/08/2021 | Yes | No |