ISRCTN98152468 https://doi.org/10.1186/ISRCTN98152468

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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(s)
Respiratory system mechanics (compliance and resistance).

Key secondary outcome(s))
Arterial partial pressure of Carbon Dioxide (pCO2).

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

Healthy volunteers allowed
No

Age group
Neonate

Sex
Not Specified

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)

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

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