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

Plain English summary of protocolNot provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

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