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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

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