ISRCTN84734652 https://doi.org/10.1186/ISRCTN84734652

Diaphragm ultrasound and trends In electrolyte disorders and transthyretin level as a method to predict ventilation outcome in children: the prospective observational cohort study

Submission date	**Recruitment status**	[X] Prospectively registered
10/07/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/07/2018	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
12/03/2019	Respiratory	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The diaphragm is a dome-shaped sheet of muscle that plays a vital role in breathing. Diaphragm dysfunction worsens outcomes in mechanically ventilated patients (breathing supported using a machine). However, the clinical impact of changes in diaphragm structure and function due to mechanical ventilation is unknown. In addition sick children who are provided with mechanical ventilation often have moderate or severe malnutrition together with deterioration of electrolyte levels and are at risk of refeeding syndrome (metabolic disturbances) and severe hypophosphatemia (low phosphate levels in the blood). The aim of this study is to find out whether diaphragm atrophy developing during mechanical ventilation leads to prolonged ventilation.

Who can participate?
Patients aged 1 month - 6 years who are mechanically ventilated

What does the study involve?
All participants receive the same treatment of underlying disease. Diaphragm thickness at the end of inspiration (breathing in) and diaphragmatic excursion (movement of the diaphragm during breathing) are measured on the 1st, 3rd, 5th and then every five days during mechanical ventilation by ultrasound. At the same time the levels of phosphorus, magnesium, calcium, potassium and sodium in the blood are measured.

What are the possible benefits and risks of participating?
The results of this study may improve the understanding of the role of diaphragm dysfunction during mechanical ventilation and its impact on malnutrition and electrolyte levels. There are no risks expected.

Where is the study run from?
Lviv Regional Clinical Children Hospital "OCHMATDYT" (Ukraine)

When is the study starting and how long is it expected to run for?
July 2018 to July 2019

Who is funding the study?
Danylo Halytskyy Lviv National Medical University (Ukraine)

Who is the main contact?
Dr Olha Filyk
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1-2018

Study information

Scientific Title
Diaphragm ultrasound and trends In electrolyte disorders and transthyretin level as a method to predict ventilation outcome in children: the prospective observational cohort study

Study objectives
The duration of mechanical ventilation stay in the intensive care unit, and the frequency of complications in children depend on the degree of diaphragm atrophy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board of Danylo Halytskyy Lviv National Medical University, 31/01/2018, protocol №1-2018

Study design
Prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Acute respiratory failure

Interventions
Diaphragm thickness (Tdi) at end of inspiration and diaphragmatic excursion will be measured on 1st, 3rd, 5th and than every five days during mechanical ventilation by ultrasound in children requiring invasive mechanical ventilation, and inspiratory effort will be assessed by thickening fraction. At the same time levels of phosphorus, magnesium, calcium, potassium and sodium in the patient's plasma will be evaluated.

Intervention Type
Other

Primary outcome measure
The time to liberation from ventilation; every day from baseline the trialists will check the possibility of weaning patients from mechanical ventilation (its mean decreasing of parameters during mechanical ventilation and extubation - both together) and then take into account duration of mechanical ventilation

Secondary outcome measures
1. Complications (reintubation, tracheostomy, prolonged ventilation, or death); the trialists will check for the presence of these adverse events every day from baseline, then on day 28 of hospitalisation and until patient is discharged from the hospital
2. Electrolyte levels (calcium, potassium, sodium measured using mixed venous blood test on

acid-base balance; phosphorus and magnesium measured using biochemical venous blood test) and transthyretin level (blood samples analysed by ELISA); checked on 1st, 3rd, 5th, 7th, 9th and then every five days of mechanical ventilation until patient is weaned from mechanical ventilation and on 3rd and 5th days after weaning

Overall study start date
09/07/2018

Completion date
01/07/2019

Eligibility

Key inclusion criteria
1. Presence of informed consent from legal representatives of the child to take part in trial
2. Children aged 1 month - 6 years old
3. Acute respiratory failure with clinical data of excessive work of breathing, laboratory data of hypoxemia, hypercapnia or both, acidosis which leads to need to provide invasive mechanical ventilation

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Months

Upper age limit
6 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Absence of informed consent from legal representatives of the child to take part in trial at any stage of this trial
2. Acute or chronic respiratory failure without need to provide invasive mechanical ventilation
3. Congenital heart diseases
4. Neuromyotonia according to results of electromyography

Date of first enrolment
15/07/2018

Date of final enrolment
01/06/2019

Locations

Countries of recruitment
Ukraine

Study participating centre
Lviv Children Clinical Hospital "OCHMATDYT"
Lysenka str., 31
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Sponsor information

Organisation
Danylo Halytskyy Lviv National Medical University

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Sponsor type
University/education

Website
http://meduniv.lviv.ua/index.php?option=com_content&view=article&id=156&Itemid=232&lang=uk

ROR
https://ror.org/0027cag10

Funder(s)

Funder type
University/education

Funder Name

Results and Publications

Publication and dissemination plan
After enrolling all 50 participants or ending the trial the trialists will prepare articles and disseminate trial results at conferences.

Intention to publish date
01/08/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Olha Filyk (doctor_555@ukr.net). Type of data will be patient cards and researcher tables which will be available on request 20 years after the research ends, the data will become available after end of the research. The consent from participants (their parents or legal representative of the patient) will be obtained before their enrolling into trial. Data will be anonymised in any published results of this investigation. This study has no ethical or legal restrictions.

IPD sharing plan summary
Available on request