Fluids in mechanically ventilated children with acute infectious lung disease: how dry should they be?

Published: 26-05-2016
Last updated: 20-04-2024

This research project aims to determine the feasibility of setting up a randomized controlled trial to study the effects of different fluid management protocols on the outcome of mechanically ventilated pediatric patients with acute infectious lung...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ancillary infectious topics
Study type	Interventional

Summary

ID

NL-OMON44104

Source
ToetsingOnline

Brief title
Fluids in pediatric acute infectious lung disease

Condition

- Ancillary infectious topics
- Electrolyte and fluid balance conditions
- Respiratory tract infections

Synonym
lower respiratory tract infection, pneumonia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Stichting Kinder Intensive Care (via Ammodo Stichting)

Intervention

Keyword: children, critical illness, Fluid balance, respiratory insufficiency

Outcome measures

Primary outcome

The main study parameters are (cumulative) fluid balance and body weight during

the first week of mechanical ventilation.

Secondary outcome

The secondary study parameters are in preparation of the larger multi-center

RCT and include:

- Mortality

- Duration of mechanical ventilation

- Oxygenation indices (for which ventilation settings and blood gas analyses

are assessed; taking blood gases is part of standard care in the PICU, no extra

invasive blood punctions will be needed)

To determine the feasibility of the experimental treatment arm, we aim to study:

- In- and exclusion rate

- Adherence to treatment arms

- Need for fluid bolus

- Need for diuretics

- Hemodynamic indices (blood pressure, heart rate, medication)

- Occurrence of electrolyte imbalances (blood gas analyses are part of standard

clinical care, see above)

Study description

Background summary

Severe acute infectious lung disease in children often leads to admission to the PICU for mechanical ventilation. During the course of disease these patients, both adult and pediatric, are prone for development of fluid overload. Fluid overload is notoriously known to be associated with adverse effects on disease outcome, such as mortality and longer duration of mechanical ventilation. In adults this has also been tested in a randomized controlled trial with patients receiving either restrictive fluid treatment or a more liberal approach. Restrictive fluid administration led to improved disease outcome; shorter duration of mechanical ventilation and better oxygenation. As there are pronounced differences in fluid homeostasis and nutrient requirements between children and adults, these findings cannot be readily compared to the pediatric population. Research into this subject in the pediatric population is therefore essential to determine optimal fluid treatment.

Study objective

This research project aims to determine the feasibility of setting up a randomized controlled trial to study the effects of different fluid management protocols on the outcome of mechanically ventilated pediatric patients with acute infectious lung disease. Specifically, this implies lowering the standard fluid intake in these children in order to avoid fluid overload and evaluating whether this is a feasible and achievable goal.

Study design

An investigator-initiated single-center prospective feasibility and pilot study in preparation of a (multi-center) randomized controlled trial. The study will be conducted in the pediatric intensive care unit (PICU) of the Emma Children*s Hospital, Academic Medical Center at the University of Amsterdam. Within 12 hours after starting mechanical ventilation, patients will be randomized to either of the fluid treatment regimes and treated accordingly.

Intervention

Patients will receive a restrictive fluid regimen consisting of 70% of normal fluid recommendations or a liberal fluid regimen consisting of >85% of normal fluid recommendations. This fluid treatment regimens were chosen in such a way that caloric requirements can still be met. In children below 1 year old, or

children from 0-10 kg of weight, the calorie intake is set slightly higher, as these infants need relatively more energy per kg body weight.

Study burden and risks

The possible risks in this study are hypotension (and/or cardiovascular instability) or electrolyte imbalances. It is our perception however, that these risks (of the intervention) are comparable to the current standard clinical practice (control group) and that the interventional treatment will rather benefit than harm the subjects. Therefore, we believe that the benefits of this study are greater when compared to the potential risks.
We specifically chose this patient group for this study as this group of patients is notoriously known to develop fluid overload. We chose to include only patients with acute infectious respiratory disease and exclude patients with cardiac comorbidities as these patients often develop fluid overload due to cardiogenic failure. This selection of patients creates a more homogeneous and reproducible patient cohort with similar illnesses and causes of fluid overload.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Signed informed consent by the parents or legal caretakers
- Admitted to the pediatric intensive care unit (PICU) of the Emma Children*s Hospital, Academic Medical Center, Amsterdam, The Netherlands
- Intubated and mechanically ventilated, with an anticipated duration of mechanical ventilation of at least 72 hours at enrolment (as judged by the investigator or pediatrician on duty).
- Patients with acute infectious lung disease, including (suspected) viral, bacterial or fungal infection

Exclusion criteria

-Patients in need of a particular fluid regimen (either restrictive or liberal) due to their medical history (e.g. cardiovascular disease and/or congenital (cyanotic) heart disease)
- Use of previous and/or maintenance diuretic treatment
- Ongoing (fluid) resuscitation for shock on admission
- Acute kidney injury with need for renal replacement therapy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-10-2016
Enrollment:	34
Type:	Actual

Ethics review

Approved WMO Date:	26-05-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL55053.018.16