Early mobilization of mechanically ventilated critically ill patients aimed at optimizing recovery and reduce stay on the Thorax Intensive Care Unit: Thekla as intervention

Published: 06-10-2009
Last updated: 04-05-2024

Objective: To study the effect(s) of Thekla use as a mobilization device in a thorax intensive care setting on mechanicallyventilated critically ill patients and see if this leads to a reduction on TICU stay. Outcomes could possibly stimulate...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Therapeutic procedures and supportive care NEC
Study type	Interventional

Summary

ID

NL-OMON32447

Source
ToetsingOnline

Brief title
Thekla on the TICU

Condition

- Therapeutic procedures and supportive care NEC

Synonym
Post-operative cardiac rehabilitation

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Tilcentrum;te Vierhouten en Center Novu;Ministerie van Economische Zaken

Intervention

Keyword: Critically-ill, Intensive-care, Thekla, Verticalization

Outcome measures

Primary outcome

HR, BP, pH, pCO2, pO2, BE,B, HCO3, sO2, length of stay on TICU, costs-benefits,

staff and patient experience

Secondary outcome

n/a

Study description

Background summary

Two previous descriptive studies have been conducted. One at the Universitatsklinik Essen *Bewegingstherapie en mobilisatie in een vroeg stadium bij polytraumapatienten met de Thekla-revalidatierolstoel; Wolfgang Schirsching, Hans-Jurgen Wihs* and the other at the MST. Both studies failed in providing evidence based conclusions. However experience indicates that mobilizing critically ill patients in an early stage of recovery with the Thekla, may positively contribute to postoperative recovery.

No studies regarding the Thekla have been published in scientific journals. Similar studies involving other verticalization devices have been conducted and published. However, these numbers are small. The results of two studies involving verticalization are summarized in an overview. These previous studies suggest that there may be a positive effect of verticalization on the physiological processes in critically ill patients. This invites for further research. The study *Thekla on the TICU* can be considered a follow up study.

The social relevance of this study is covered by investigating length of stay on TICU, patient experiences and medical changes, staff experience (labour related aspects) and a cost-benefit analysis will be made. To our knowledge, these afore mentioned aspects have not been studied previously.
Mobilizing mechanically ventilated critically ill patients is accompanied by risks. These patients become easily unstable and death is close. Before initiating mobilizations, safety aspects should be considered. Studies done by Stiller and Phillips give a clear overview of the aspects that need to be covered prior and during mobilizing critically ill patients on an intensive care unit. These studies include a chart that serves as a guideline to safely mobilize these patients.

Study objective

Objective: To study the effect(s) of Thekla use as a mobilization device in a thorax intensive care setting on mechanically ventilated critically ill patients and see if this leads to a reduction on TICU stay. Outcomes could possibly stimulate the mobilization of patients with the Thekla.

To quantify the effect(s) and analyze the efficacy of Thekla use in an early stage of recovery on mechanically ventilated critically ill patients on the Thorax Intensive Care Unit within a study duration of 4 months. This will be realized by means of recordings, blood gas analysis, data analysis, questionnaires and a literature study.

Sub-objectives:
- Cost-benefit analysis
- Evaluate Thekla experience of nursing staff
- Measure the effects on the circulatory and respiratory system
- Evaluate patient experience of Thekla mobilizations

Study design

Randomized controlled pilot study

Intervention

Thekla mobilizations (60° verticalization for >=15 minutes) and regular therapy (n=15) vs. regular therapy (n=15)

Study burden and risks

Thekla verticalization does increase the risk of becoming hemodynamic unstable. Upon TICU discharge each patient from the intervention group is asked to fill in a questionnaire. Some of these patients will also be questioned orally. Depending on patient response, a numeric rating scale to assess quality of life will be acquired in both groups daily. Throughout TICU stay blood samples will be acquired daily (06:00 AM) to measure blood gas values. In the intervention group one additional blood sample is taken 10 minutes after Thekla mobilization on the first 7 days. This will be withdrawn from an arterial line that is already placed, therefore no extra invasive procedures are needed. Positive effects in lung function is expected. When this study shows that use of Thekla leads to a reduction in stay on the TICU, it could be beneficial for other patients. Physical loading of nursing staff and physiotherapists may be reduced. Also financial benefits could be a positive outcome of this study, since TICU stay is expensive.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Cardiovascular criteria: resting heart rate <120 beats per minute, blood pressure <20% variability recently and normal ECG.
Respiratory criteria: SpO2 >90% and <4% recent decrease in SpO2, respiratory rate <35 breaths per minute and mechanical ventilation needs to be able to be maintained during treatment.
Additional criteria: haemoglobin stable and >4.8 gramms/dL, platelet count stable and >50,000 cells/mm3, white cell count 4,300 - 10,800 cells/mm3, body temperature <38°C, blood glucose level 3.5 -12 mmol/L, patient must not experience excessive pain/ fatigue/ shortness of breath and the emotional status must be acceptable.

Exclusion criteria

Patients receiving other interventions than regular mobilization therapy (considered to be; active, active-assisted and passive range of motion exercises for all limbs, breathing exercises, sputum clearance and transfers performed are supine to sit, from bed to chair and pre-walking exercises) provided by nursing staff and/or physiotherapists, <18 years of age, enrollment in another trial, evidence of postoperative myocardial infarction or arrhythmia, orthopedic contraindications, recent split skin graft/ flap to lower limbs or trunk, >150 kg of weight, Intra Aortic Balloon Pump, Continuous Veno - Venous Hemofiltration in groin, arterial line in groin, deep venous thrombosis, pulmonary embolism, neurological contraindications or no Dutch language proficiency.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-11-2009
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO Date:	06-10-2009
Application type:	First submission
Review commission:	METC Twente (Enschede)

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	NL29434.044.09