Magnitude and time course of physical deconditioning in severely injured or critically ill patients; A clinimetric evaluation

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Before a countermeasure or training can be developed to counteract physical deconditioning it is important to investigate more in detail the magnitude and time course of physical deconditioning and to investigate which outcome measure is most...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON33007

Source
ToetsingOnline

Brief title
Physical deconditioning in critically ill patients

Condition

- Other condition
- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

Synonym
bedrest- bounded patients, severe injured patients

Health condition

critical ill patients

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Geen geldstroom nodig

Intervention

Keyword: bed rest, critical ill, decontioning, muscle waste

Outcome measures

Primary outcome

1. Percentage of patients of the entire ICU ward eligible for clinometric

evaluation

2. Isometric muscle force: elbow flexors, knee extensors and foot dorsiflexors

using the MRC-classification added by

hand held dynamometry (microvet) if MRC>4. Using reference

values according to vd Ploeg .

3. Muscle thickness measure=Ultrasound assessment of the m. quadriceps femoris

and m. biceps brachii muscle

4. Spirometry:

a. During mechanical ventilation: respiratory strength during

in-and expiration

b. After finishing mechanical ventilation: Maximum voluntary

respiratory vital capacity

5. Modified measurement of condition: heart rate changes followed by repetitive

movements.

Secondary outcome

1. Length of stay on the intensive care unit

2. Average amount of painkillers/neuroleptic/antidepressant drugs given during

the ICU period

3. Frequency of mortality, morbidity

4. Functional independent measure

5. SF 36

6. Ultrasound assessment of the

a. diameter of the femoral artery.

b. Fibrillations

c. Density

7. Tendon reflexes ATR, PTR, BR

Study description

Background summary

Patients stay at an intensive care ward for support of their vital functions.
In most cases patients need mechanical ventilation and intensive monitoring of vital functions after severe trauma, sepsis, multiple organ failure, after cardiac surgery, infection (multi organ failure), primary and secondary pulmonary insufficiency and spinal cord injury. Since these patients are not stable their vital situation may change quickly and therefore they need intensive monitoring and care. Bed rest is a commonly prescribed activity restriction among patients in the ICU. Although bed rest may promote rest, recovery and safety, inactivity related to bed rest also may lead to complications and adverse outcomes. In the period that patients are bedridden there is a quick loss of physical condition with a decrease of muscle power and capability to move (Winkelman 2007). In combination with inflammatory diseases, the neuromuscular abnormalities culminating in skeletal muscle weakness are even more pronounced (Deem 2006, Ferrando et al 2006), in combination with SIRS (Systemic Inflammatory Response Syndrome) critical illness polyneuropathy may develop in 20% to 50% of patients in major ICU*s (Bolton 2005).

Furthermore, critically ill patients become more susceptible for tromboembolic complications, pneumonia and pressure ulcers (Robson et al 2003). It is known from studies that even in healthy volunteers 2 weeks of bed rest results in a reduction of muscle size, length and strength (Mulder et al 2006, Akima et al 1997). In cases of inactivity it has been shown that the muscle architecture shifts from slow twitch (aerobic) to fast twitch (anaerobic) fibres so that after the bed rest subjects lose endurance capacity (Gallagher et al 2005, Bigard et al 1998). Researchers in our own group found that bed rest causes a deterioration of the shape of the cardiovascular system (De groot et al 2006) and induces a reduction of blood vessel diameters (Bleeker et al 2004 and 2005). Patients with a major trauma or critically illness will lose even more since they are often in catabolic conditions caused by wounds and inflammation. In addition, bedridden patients on intensive care units become frequently mentally disturbed. They lose their sense of day and night and they are exposed to an environment that is frightening with surrounding noises all day and night (Walder et al 2007). Patients that stay longer than 1 week on an intensive care have 50% chance to come into a state of delirium that is called intensive care psychosis (Ouimet et al 2007, Pandharipande 2005, 2006).
The current management to counteract this physical and mental deterioration consists of single daily physiotherapy sessions of approximately 20 min. This intensity of training is not sufficient to counteract above-mentioned negative physiological processes. Early and more intensive physical training is needed.

Study objective

Before a countermeasure or training can be developed to counteract physical deconditioning it is important to investigate more in detail the magnitude and time course of physical deconditioning and to investigate which outcome measure is most indicative for physical deconditioning In this study we will investigate the size of the population on an intensive care ward of an academic hospital that is at risk of physical deconditioning. In addition we will investigate the extent and time course of physical deconditioning.

Study design

prospective clinometric evaluation

Study burden and risks

Al measurements are non-invasive. The burden for each patient is the physical examination and measurement of condition.

Contacts

Public
Academisch Medisch Centrum

Reinier Postlaan 4
6500 HB
Nederland
Scientific
Academisch Medisch Centrum

Reinier Postlaan 4
6500 HB
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

admitted on ICU
> 18 years
> 4 days of mechanical ventilation
consiouss

Exclusion criteria

Delirium
Sedation
Pain

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2010
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	03-05-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL27179.091.09