Prevalence of the post-intensive care syndrome in a Dutch suburban cohort and a patients perspective on prevention and treatment interventions

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To explore the long-term prevalence of PICS in a representative sample of Dutch adult survivors intensive care treatment

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

Summary

ID

NL-OMON42477

Source
ToetsingOnline

Brief title
Retrospective questionnaire of the prevalence of PICS

Condition

- Other condition

Synonym
intensive care related complications, Post intensive care syndrome

Health condition

Combinatie van cogitieve, psychische en fysieke facoren. Tezamen met effecten op sociale factor en werk-inkomen

Research involving

Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: Op geheel vrijwillige basis uitgevoerd door ondergetekenden

Intervention

Keyword: intensive care, Post-ICU- syndrome, ptss, retrospective

Outcome measures

Primary outcome

To explore the long-term prevalence of PICS in a representative sample of Dutch

adult survivors after intensive care treatment

Questionaire consists of:

- Health related quality of life using the Short Form 36 Version 2 (SF-36)

questionnaire

- Health related quality of life using the EQ5-D questionnaire

- Physical impairments/rehabilitation using the SF-36 questionnaire

- Prevalence of post-traumatic stress using the Impact of Event Scale (IES)

questionnaire

- A novel question set designed to determine changes in family circumstances,

socio-economic stability and care requirements.

- Novel questions regarding the prevalence of a intervention.

For the complete questionnaire, see the attachment.

Secondary outcome

Treatment related information

- Age

- Sex

- BMI

- Race

- ICU stay (days)

- APACHE II / APACHE IV / SOFA score.

- scoring of delirium

- days of mechanical ventilation (endotracheal vs tracheotomy)

- noninvasive ventilation

- use of vasopressors

- use of (analgo)-sedatives (remifentanil/ propofol etc)

- use of analgetics (morfine / paracetamol / sufentanyl / fentanyl)

- use of Haldol / Is delirium present during ICU stay

- RASS score (if applicable)

Study description

Background summary

Recently a single term to identify the presence of one or more of these impairments was acknowledged, it is called the *post-ICU syndrome* (PICS). To date however most studies focused on a single specific impairment instead of focusing on the complete sequalae of PICS. This has led to a widespread, but diffuse knowledge of different ICU related complications.
Because until recently there was no uniform term, observational and intervention studies focused on specific subsets of PICS. Interventions to improve different impairments may be addressed by the following interventions: ICU diaries, early in-ICU psychological intervention, and post-ICU coping skills training, and intensive care follow-up clinics. To our knowledge evidence-based guidelines are lacking. Despite this recent studies that demonstrated several tools that might intervene in the developement of PICS, a

recent study in the UK showed that survivors of critical illness face a negative impact on employment and commonly have a care requirement after discharge from hospital. This last study pointed out that a broader perspective on PICS is essential before studying possible intervention methods (for example intensive care follow-up clinics).
We therefore believe that more research of appropriate methodological quality using PICS as a syndrome is needed. Subsequently a multi-disciplinary and multilevel-based approach is paramount to a successful prevention and intervention practice.

Study objective

To explore the long-term prevalence of PICS in a representative sample of Dutch adult survivors intensive care treatment

Study design

Multi-centre retrospective questionnaire-based study in survivors after ICU admission, respectively 1, 6 , 12, and 24 months after ICU discharge.

Study burden and risks

There are no risks associated with this retrospective questionnaire-based approach. Using this method, no additional risk or burden is involved, waiver of consent is used and no prior written informed consent is required.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Patients between 18-65 years of age. Patients > 65 were not included because of 2 reasons: The survey has a low response rate in the >65 population, and because we wanted to determine the impact on employment and economic impact.
- Patients admitted for the first time to the ICU during their hospital stay with an ICU length of stay >= 48 h and fulfilling the following criteria:
- Severe sepsis and septic shock was defined according to previously published criteria6.
- Patients who received a tracheotomy during their ICU stay
- Patients who were diagnosed with ARDS during their hospital stay
- Patients with prolonged mechanical ventilation (> 7 days)

Exclusion criteria

- Patients younger than 18 years
- who were pregnant
- known participation in another randomized controlled biomedical study
- elective postoperative admission, uncomplicated during ICU admission

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2016
Enrollment:	500
Type:	Anticipated

Ethics review

Approved WMO

Date:	23-03-2016
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL56169.101.15