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Long-term consequences of pain, anxiety and agitation in older, critically ill patients after a stay on an intensive care unit

Submission date
27/06/2011

Recruitment status
No longer recruiting

Registration date
06/07/2011

Overall study status
Completed

Last Edited
19/02/2016

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Intensive care medicine often enables the survival of older critically ill patients. However, relatively little is known about the long-term outcomes following treatment in the intensive care unit (ICU). Survival alone is not the only important outcome following an ICU stay. Stress experienced in the ICU and the severity of illness or injury can have long-term consequences. Over the long term, discomfort experienced in the ICU and stressful memories of an ICU stay can lead to anxiety, depression, and impaired quality of life. Until now, few studies have examined the long-term outcomes after ICU admission in older critically ill patients. Pain, anxiety and agitation are important stress factors for many critically ill patients and can have consequences for quality of life, but they have rarely been studied in older critically ill patients in the ICU. This study examines the relationship between the ICU stay and pain, anxiety and agitation in older critically ill patients, and addresses whether experiences in the ICU can cause more serious chronic conditions after discharge from the hospital.

Who can participate?
Critically ill patients aged 65 and over who have had an ICU stay of at least 48 hours, and a sample of people aged 65 and over who have not been admitted to an ICU for the last 15 years.

What does the study involve?
Patients are followed up one year after their discharge from the hospital. Their pain experiences, levels of anxiety and agitation, quality of life, and use of the health care system are assessed in order to detect relationships between these outcomes and their ICU experiences. Data is collected at the following intervals: during their ICU stay, and 1 week, 6 and 12 months after hospital discharge. Similar data is also collected from a sample of older people who have not been admitted to an ICU for the last 15 years.

What are the possible benefits and risks of participating?
No risks to the participants are anticipated. During the interview, the participants are confronted with memories and experiences of the ICU, which may be upsetting. If this is the case, the interview is stopped. The participants are offered professional support, for example

medical and/or psychological care, information, etc. It is also possible that remembering unpleasant experiences can be an important step towards coming to terms with their stay on the ICU. Therefore, the interviews are geared to the needs and abilities of the participants, who are thoroughly informed that they may interrupt the interview or stop it altogether.

Where is the study run from?
The study is conducted in the interdisciplinary ICU of a Swiss university hospital, as well as at 12 follow-up clinics

When is the study starting and how long is it expected to run for?
December 2008 to April 2011

Who is funding the study?
University Hospital of Bern and the Swiss Red Cross (Switzerland)

Who is the main contact?
Marie-Madlen Jeitziner

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Long-term consequences of pain, anxiety and agitation in older, critically ill patients after a stay on an intensive care unit - a prospective, observational study

Study objectives

Modern methods in intensive care medicine often enable the survival of older critically ill patients. The short-term outcomes for patients treated in intensive care units (ICUs), such as survival to hospital discharge, are well documented. However, relatively little is known about subsequent long-term outcomes. Pain, anxiety and agitation are important stress factors for many critically ill patients. There are very few studies concerned with pain, anxiety and agitation and the consequences in older critically ill patients. The overall aim of this study is to identify how an ICU stay influences an older persons experiences later in life. More specificly, this study has the following objectives:
1. To explore the relationship between pain, anxiety and agitation during ICU stays and experiences of the same symptoms in later life
2. To explore the associations between pain, anxiety and agitation experienced during ICU stays and their effect on subsequent health-related quality of life, use of the health care system (readmissions, doctor visits, rehabilitation, medication use), living situation, and survival after discharge and at 6 and 12 months of follow-up

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cantonal Ethics Commission of Bern (Kantonale Ethischen Kommission Bern), 01/09/2008, Ref. Nr. KEK-BE: 128/08

Study design
Prospective observational longitudinal study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
ICU patients

Interventions
1. Background data will be gathered via medical records and questionnaires
2. Medical and nursing staff will gather daily routine data regarding pain, anxiety, and agitation, along with any other information relevant to usual care in the ICU
3. Collection of data concerning pain, anxiety and agitation will be carried out by the staff who regularly care for the patients
4. For this study these caregivers have received special training

5. Data about the outcome indicators will be collected using questionnaires 1 week, 6 months and 12 months after discharge. It should be emphasized that participants in the ICU group will be asked one week after discharge to make an assessment of both their current HR-QOL and their HR-QOL, pain, anxiety and agitation intensity, before admission to the ICU
6. One week after ICU discharge, patients in the ICU group will be contacted and interviewed
7. The interviews will be carried out only if the patients are physically and psychologically fit to be interviewed
8. If necessary, help will be provided in filling out the questionnaire
9. All data will be collected using face-to-face (baseline) and telephone (follow-up) interviews and will be collected by 4 trained interviewers
10. The baseline interviews with all critically ill patients will take place in the hospital
11. All other interviews for both groups will take place by telephone
12. The SF-36 and HADS-D will be mailed to all participants. In order for them to prepare themselves for the interview, both groups will be informed of the general nature of the questions ahead of time
13. Because unanswered questions would affect the evaluation of the questionnaires, an interviewer will check to ensure that all questions have been answered, and follow up in cases where information is lacking. If questionnaires are not returned, reminders will be sent to the participants.
14. Data will be collected at the following intervals: during ICU, 1 week, 6 and 12 months after hospital discharge

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Pain, anxiety and agitation during an ICU stay
2. During the ICU stay, pain, anxiety and agitation will be measured in the ICU group
3. In patients unable to verbally express themselves, pain intensity will be measured using a behavioural pain scale employing three behavioural parameters:
3.1. Mimic
3.2. Body movement
3.3. Muscle tone
4. The intensity of the behavioural parameters will be assessed on the basis of a four-point Likert scale: each characteristic will be rated as weak or absent, moderately severe, severe, or very severe
5. Anxiety will be assessed using a numeric rating scale (0-10) (0=no anxiety to 10=worst possible anxiety)
6. Agitation during the ICU stay will be measured using the German version of the Richmond Agitation-Sedation Scale (RASS), which has 10 levels, ranging from -5: unarousable (no response) to +4: combative (danger to staff)
6. This scale has proven reliable for the assessment of critically ill patients in the ICU, with strong interrater reliability and criterion, construct, and face validity
7. The Confusion Assessment Method for the ICU (CAM-ICU) will be used to assess delirium in the ICU, as well as general cognitive abilities, focusing on the following factors: 7.1. Acute onset or fluctuating course

7.2. Inattention
7.3. Disorganized thinking
7.4. Altered level of consciousness

After discharge:
1. In line with the study aims, the following outcome indicators will be measured in both the ICU group and the comparison group:
1.1. Pain, anxiety and agitation
1.2. HRQOL
1.3. Use of the health care system (readmissions, general practitioner visits, rehabilitation, length of hospital stay), medication use, living situation and survival
2. Pain intensity will be measured with a numeric scale (NRS) (0=no pain to 10=worst possible pain), and pain frequency with a Likert-type scale (never, seldom, occasionally, often, always)
3. Anxiety will be assessed using a numeric rating scale (0-10) and the Hospital Anxiety and Depression Scale (HADS-D), which uses two subscales, an anxiety scale (HADS-A) and a depression scale (HADS-D)
4. Agitation will be measured using the Confusion Assessment Method (CAM)
5. The German or French Short Form of the Confusion Assessment Method (CAM), including a telephone version for the 6- and 12-month follow-ups, will be used for all participants
6. Health-related quality of life (HR-QOL) will be assessed using the component scores of the Short Form 36 Health Survey (SF-36). As a comprehensive, generic, 36-item instrument, the SF-36 concentrates on the subjective evaluation of health:
6.1. Physical function
6.2. Physical role function
6.3. Bodily pain
6.4. General health perceptions
6.5. Vitality
6.6. Social role function
6.7. Emotional role function
6.8. Mental health
7. The items vary from yes/no questions to hose offering 6 levels of choice
8. All subscales have been adapted to yield assessment values between 0 and 100

Secondary outcome measures
1. Use of the health care system (readmissions, general practitioner visits, rehabilitation, length of hospital stay)
2. Medication use
3. Living situation and survival

Overall study start date
01/12/2008

Completion date
01/04/2011

Eligibility

Key inclusion criteria

1. Minimum age of 65 years
2. Have had an ICU stay of at least 48 hours (ICU group) or no stay for the last 15 years (comparison group)
3. Be able to speak and read either German or French, and live in Switzerland

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
150 ICU patients and 150 persons for the comparison group

Key exclusion criteria
1. Temporary tracheostomies
2. Chronic mechanical ventilation
3. Illness-related cognitive impairment (dementia)
4. Psychotic illnesses including delusions and changes in mental state
5. Potentially terminal illnesses such as lung or heart diseases and cancer

Date of first enrolment
01/12/2008

Date of final enrolment
01/04/2011

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital Bern (Inselspital)
Bern
Switzerland
3010

Sponsor information

Organisation

University Hospital Bern (Switzerland)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.cvrc.dkf.unibe.ch/content/

ROR
https://ror.org/01q9sj412

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital of Bern (Direktion Pflege / MTT) (Switzerland)

Funder Name
Swiss Red Cross (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	02/09/2011		Yes	No