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Algorithm-based diagnosis and symptom-orientated treatment of delirium in intensive care unit (ICU)-patients

Submission date	Recruitment status	[_] Prospectively registered
29/08/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/01/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/05/2021	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Algorithm-based diagnosis and symptom-orientated treatment of delirium in intensive care unit (ICU)-patients

Study objectives
Current hypothesis as of 26/06/2015:
Adherence to delirium monitoring as an additional level of care results in an improved clinical outcome.
Secondly we hypothesize that symptom-orientated treatment of delirious deficits results in improved clinical outcome.

Previous hypothesis:
Stepwise symptom-orientated early treatment of predelirium leads to less severity and shorter duration of delirium and better outcome.

On 26/06/2015 the following changes were made to the trial record:
1. The overall trial start date was changed from 01/08/2007 to 01/02/2007
2. The overall trial end date was changed from 31/07/2009 to 31/05/2008

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local medical ethics committee (Ethikkommission Ethikausschuss 1 am Campus Charité-Mitte), 01/08/2007, ref: EA1/132/07

Study design
Prospective observational monocentre trial

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Screening for delirium in Intensive Care Unit

Interventions
Current interventions as of 26/06/2015:
Diagnosis and treatment of delirium are made according to internal hospital Standard Operating Procedures. Every patient gets a delirium screening with the use of either the:
1. Delirium Detection Score (DDS), or the
2. Confusion Assessment Method for the ICU.

Data collection in this study will be performed prospectively.. There will be a short analysis of the preliminary data collection from 2006.

Previous interventions:
Diagnosis and treatment of delirium are made according to internal hospital Standard Operating Procedures. Every patient with impaired consciousness gets a delirium screening with the use of two different scoring systems:
1. Delirium Detection Score (DDS)
2. Confusion Assessment Method for the ICU

Ongoing symptom-orientated delirium therapy will be initiated.

Data collection in this study will be performed prospectively. Final analysis of all outcome data will be performed after the anticipated end date of the trial. There will be a short analysis of the preliminary data collection every 6 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Current primary outcome measures as of 26/06/2015:
1. Mortality

Previous primary outcome measures:
1. Mortality
2. Duration of mechanical ventilation
3. Length of ICU-stay

Secondary outcome measures
Current secondary outcome measures as of 26/06/2015:
1. Incidence of delirium
2. Incidence of hypoactive delirium
3. Incidence of hyperactive delirium
4. Adherence to delirium monitoring
5. Adherence to symptom-orientated treatment of delirium
6. Duration of mechanical ventilation
7. Length of ICU-stay
8. Length of hospital stay
9. Severity of pain
10. Depth of sedation
11. Severity of illness

Previous secondary outcome measures:
1. Higher frequency of delirium detection
2. Higher frequency of hypoactive delirium diagnosis
3. Higher frequency of adequate treatment of delirium

Overall study start date
01/02/2007

Completion date
31/05/2008

Eligibility

Key inclusion criteria
Current inclusion criteria as of 26/06/2015:
All patients with an ICU stay greater than 24 hours will be included in this observational trial.

Previous inclusion criteria:
All patients with an ICU stay greater than 36 hours will be included in this observational trial.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
185

Total final enrolment
185

Key exclusion criteria
Aged less than 18 years.

Date of first enrolment
01/07/2007

Date of final enrolment
01/11/2007

Locations

Countries of recruitment
Germany

Study participating centre
Charite - Universitatsmedizin Berlin
Department of Anaesthesiology and Intensive Care Medicine
Campus Charité Mitte and Campus Virchow - Klinikum
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Sponsor information

Organisation
Charite - University Medicine Berlin (Universitatsmedizin Berlin) (Germany)

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Sponsor type
University/education

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
University/education

Funder Name
Charité Universitätsmedizin Berlin

Alternative Name(s)
Medical School - Charité - University Medicine Berlin

Funding Body Type
Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location
Germany

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to legal restrictions imposed by the Ethics Commission of the Charité – Universitätsmedizin Berlin and the data protection commissioner of the Charité – Universitätsmedizin Berlin, public sharing of study data with other researchers or entities is not allowed. This prohibits the authors from making the dataset publicly available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/10/2016	12/05/2021	Yes	No