Algorithm-based diagnosis and symptomorientated 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

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Screening

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)
- 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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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 Berlin Germany 13353

Sponsor information

Organisation

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

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

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