

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

Submission date 29/08/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/01/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/05/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Claudia Spies

Contact details

Charite - Universitätsmedizin Berlin
Department of Anaesthesiology and Intensive Care Medicine
Campus Charité Mitte and Campus Virchow - Klinikum
Augustenburger Platz 1
Berlin
Germany
13353

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claudia.spies@charite.de

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 pre-delirium 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 - Universitätsmedizin 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 (Universitätsmedizin Berlin) (Germany)

Sponsor details

Chariteplatz 1

Berlin

Berlin

Germany

10117

-

fabian.hempel@charite.de

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