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Influence of dexmedetomidine on hemodynamic parameters in critical ill patients

Submission date	Recruitment status	[ ] Prospectively registered
07/08/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/08/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/08/2017	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Delirium is a state of mental confusion that affects up to 80% of mechanically ventilated ICU patients. It is associated with prolonged ICU and hospital stay, the development of cognitive impairment and increased mortality (death rate). Therefore, early detection of delirious patients is essential for treatment. After delirium is diagnosed, the main aim is to reduce its severity and duration. Dexmedetomidine is one of the drugs which are suggested for the prevention and treatment of delirious ICU patients. The aim of this study is to investigate its possible side-effects on blood circulation using single transpulmonary thermodilution and pulse contour analysis - techniques to measure blood flow which are routinely used in ICU patients.

Who can participate?
Critically ill patients aged 18 and older with delirium after admission to the ICU

What does the study involve?
All participants are treated with dexmedetomidine. Dexmedetomidine is part of the normal routine care for ICU patients with delirium. After 2 hours the dose is increased. Blood flow measurements (transpulmonary thermodilution and pulse contour analysis) are performed at 0, 2 and 4 hours after starting dexmedetomidine treatment. When the delirium has resolved and there is no need for further monitoring or treatment on the ICU, the participants are transferred to a normal ward.

What are the possible benefits and risks of participating?
Transpulmonary thermodilution and pulse contour analysis are used to analyse the effects of dexmedetomidine and improve treatment monitoring. Only patients already equipped with the PiCCO heart output monitor are chosen for this study. These are patients in whom heart and blood volume monitoring is necessary (e.g. sepsis, acute respiratory distress syndrome, acute pancreatitis, burns, etc.). Therefore there are no additional risks due to the placing of catheters. As soon a local or systemic infection is suspected, the catheters are removed.

Where is the study run from?
Technical University of Munich (Germany)

When is the study starting and how long is it expected to run for?
January 2016 to August 2017

Who is funding the study?
Technical University of Munich (Germany)

Who is the main contact?
1. Dr Alexander Herner
2. Prof. Wolfgang Huber

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DEX

Study information

Scientific Title
Influence of dexmedetomidine on hemodynamic parameters in critical ill patients with delirium: a single center prospective study

Study objectives
Dexmedetomidine infuences cardiac performance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Fakultät für Medizin, Technische Universität München, 26/06/2012, ref: 5384/12s

Study design
Prospective observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Critically ill patients with occurring delirium after admission to ICU

Interventions
Twelve consecutive ICU patients with agitated delirium according to Richmond Agitation Sedation Scale (RASS) were assigned to receive dexmedetomidine (DEX). Dexmedetomidine is part of the normal routine care for ICU-patients with delirium. According to the manufacturer's suggestion DEX was administered initially at 0.3µg/kg/h. After 2h the dosage of DEX was increased to 0.7µg/kg/h to achieve RASS-levels between -2 and 0. Hemodynamic measurements (transpulmonary thermodilution and pulse contour analysis) were performed 0h, 2h and 4h after initiation of DEX. In case of the pre-defined stopping criteria (MAP<65mmHg and/or HR<60/min) DEX was stopped. In this case hemodynamic measurements were performed immediately after stopping of DEX and 2h after withdrawal. There was no loading dose of DEX. After resolution of

delirium and no need for further monitoring or treatment on the ICU, the patients are transferred to a normal ward. Further interviews or observations are not planned.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dexmedetomidine

Primary outcome measure
Cardiac power index is measured using the transpulmonary thermodilution technique (PiCCO) at the individual maximum dosage of dexmedetomidine (0.3µg/kg/h or 0.7µg/kg/h) and compared to baseline values (dexmedetomidine, 0 µg/kg/h)

Secondary outcome measures
1. Cardiac index (CI) is measured using the transpulmonary thermodilution technique (PiCCO)
2. Systemic vascular resistance index (SVRI) is measured using the transpulmonary thermodilution technique (PiCCO)
3. Global end diastolic volume index (GEDVI) is measured using the transpulmonary thermodilution technique (PiCCO)
4. Extravascular lung water index (EVLWI) is measured using the transpulmonary thermodilution technique (PiCCO)
5. Pulmonary vascular permeability index (PVPI) is measured using the transpulmonary thermodilution technique (PiCCO)
6. Heart rate (HR) is measured permanently via 5-French thermistor tipped arterial catheter
7. Mean arterial pressure (MAP) is measured permanently via 5-French thermistor tipped arterial catheter

Transpulmonary thermodilution measurements were performed at following timepoints and concentrations:
0h: dexmedetomidine: 0 µg/kg/h
2h: dexmedetomidine: 0.3µg/kg/h
4h: dexmedetomidine: 0.7µg/kg/h
2h after therapy with dexmedetomidine was stopped
or as soon as predefined termination criteria (HR <60/min and/or MAP<65mmHg) were fulfilled

Overall study start date
01/01/2016

Completion date
01/08/2017

Eligibility

Key inclusion criteria

Critically ill patients (18 years and older) with occurring delirium after admission to ICU. For delirium screening the Confusion Assessment Method (CAM-ICU) and Richmond Agitation-Sedation-Scale (RASS) were used.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
In total 12 patients were included in this study

Key exclusion criteria
1. Younger than 18 years
2. Pregnancy
3. Known drug intolerance or allergy against dexmedetomidine
4. Increased intracranial pressure
5. Patients with cerebrale pathology, which changes the controllability of sedation or die consciousness
6. Myasthenia Gravis
7. Cerebellar or spinal Ataxia
8. Enzyme related disorders that are associated with a severe decreased activity of UDP-glucoronyltransferase (e.g. M. Crigler- Najjar)
9. Chronic liver insufficiency CHILD A, B or C

Date of first enrolment
01/02/2016

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
Germany

Study participating centre
Technical University of Munich
Intensive care unit, II. Medical Department
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Sponsor information

Organisation
Klinikum rechts der Isar der TU München

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04jc43x05

Funder(s)

Funder type
University/education

Funder Name
Klinik und Poliklinik für Innere Medizin II, Klinikum rechts der Isar der TU München

Results and Publications

Publication and dissemination plan
Additional documents (such as study protocol, statistical analysis plan) are/will be available upon request from Alexander Herner and Wolfgang Huber. Planned publication of results in a peer reviewed journal.

Intention to publish date
01/08/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Alexander Herner and Wolfgang Huber.

IPD sharing plan summary

Available on request