ISRCTN57998533 https://doi.org/10.1186/ISRCTN57998533

The effects of dexmedetomidine on cerebral blood flow and cerebral metabolic rate

Submission date	Recruitment status
28/06/2011	No longer recruiting
Registration date	**Overall study status**
10/10/2011	Completed
Last Edited	**Condition category**
16/06/2017	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Large studies show that the drug dexmedetomidine can provide sedation without reducing respiration (breathing) and affecting consciousness , but some studies have reported that dexmedetomidine reduces cerebral (brain) blood flow, partly due to constriction of blood vessels. Cerebral metabolic rate (rate of energy expenditure) also decreased. However, there is very little information about the effects of dexmedetomidine on cerebral blood flow and cerebral metabolic rate in traumatic brain injury patients. Therefore, the aim of this study is to gather information on the effects of dexmedetomidine on cerebral blood flow and cerebral metabolic rate in non-traumatic brain injury patients and traumatic brain injury patients separately.

Who can participate?
Non-traumatic brain injury patients and traumatic brain injury patients

What does the study involve?
Participants are randomly allocated to be treated with either dexmedetomidine or dexmedetomidine combined with dopamine. Ultrasound is used to measure cerebral blood flow, and blood samples are to measure cerebral metabolic rate before and after dexmedetomidine treatment.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Shanghai Sixth People's Hospital (China)

When is the study starting and how long is it expected to run for?
September 2011 to November 2011

Who is funding the study?
Shanghai Sixth People's Hospital (China)

Who is the main contact?
Miss Junhui Ji

Contact information

Type(s)
Scientific

Contact name
Miss Junhui Ji

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The effects of dexmedetomidine on cerebral blood flow and cerebral metabolic rate

Study objectives
The objective of this study is to observe the effects of dexmedetomidine on cerebral blood flow and cerebral metabolic rate in non-traumatic brain injury patients and traumatic brain injury patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Shanghai Sixth People's Hospital, Shanghai Jiaotong University, 14/09/2011, ref: 2011-50

Study design
Randomised prospective case-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Traumatic brain injury (TBI), cerebral blood flow (CBF) and cerebral metabolic rate (CMR)

Interventions
The German Philips Intellivue MP20 multi-function monitor is used for continuous monitoring of SBP, DBP, MAP, HR, RR and SpO2, and color Doppler ultrasound (esaote MyLab40, Italy, frequency 7.5 ~ 10MHZ) is used to measure carotid artery and vertebral artery blood flow at presedation, 70 minutes of administration of dexmedetomidine and 4 hours after discontinuing dexmedetomidine, cerebral blood flow will be obtained by the conversion formula. Dexmedetomidine is injected by a Braun 8714827 micro-pump for a loading dose of 1mg/kg (infusion 10 min), then a maintenance dose of 0.4mg.kg-1.h-1 (infusion 2h). In the dexmedetomidine group, dopamine is pumped to maintain blood pressure at normal low levels once the SBP is less than 90 mmHg or DBP is less than 50mmHg, and in the dexmedetomidine combined with dopamine group and traumatic brain injury patients group, dopamine is pumped to maintain blood pressure at the level before dexmedetomidine administration. After discontinuing infusing dexmedetomidine, dopamine can be gradually tapered to discontinue. Jugular vein and femoral arterial blood are analyzed by German GEM 3000 blood gas analyzer to measure cerebral metabolic rate by formula. Follow-up monitoring SBP, DBP, MAP, HR, RR and SpO2 of patients after discontinued infusing dexmedetomidine for 1 day.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Cerebral blood flow

Key secondary outcome(s))
1. Cerebral metabolic rate of oxygen
2. The dosage of dopamine
3. Diastolic blood pressure
4. Systolic blood pressure
5. Mean arterial pressure
6. Heart rate
7. Respiratory rate
8. Oxygen saturation
9. PaCO2

Completion date
20/11/2011

Eligibility

Key inclusion criteria

1. Electrocardiogram (ECG) examination was normal, no hypotension, no bradycardia, etc
2. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Brain tumor, hypertensive cerebral hemorrhage and non-traumatic brain injury patients
2. Patients combined heart failure, liver dysfunction, renal insufficiency, cardiac arrhythmias
3. Patients combined severe primary liver disease, severe primary renal disease, severe primary hematopoietic system diseases or mental illness
4. Pregnancy or breastfeeding women
5. Patients with allergies
6. Patients participating in other clinical trials

Date of first enrolment
20/09/2011

Date of final enrolment
20/11/2011

Locations

Countries of recruitment
China

Study participating centre
Shanghai Sixth People's Hospital
Shanghai
China
200233

Sponsor information

Organisation

Shanghai Sixth People's Hospital (China)

ROR
https://ror.org/049zrh188

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Shanghai Sixth People's Hospital (China)

Results and Publications

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?
Results article	results	01/09/2013		Yes	No