

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

Submission date 28/06/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 10/10/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 16/06/2017	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> 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

Contact details

Department of Anaesthesiology and ICU

Shanghai Sixth People's Hospital

600 Yi-Shan Road

Shanghai

China

200233

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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

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 pre-sedation, 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 measure

Cerebral blood flow

Secondary outcome measures

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

Overall study start date

20/09/2011

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

Age group

Adult

Sex

Both

Target number of participants

50

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)

Sponsor details
c/o Dr Xuemin Wang
Department of Anaesthesiology and ICU
Shanghai Sixth People's Hospital
600 Yi-Shan Road
Shanghai
China
200233

Sponsor type
Hospital/treatment centre

Website
<http://www.6thhosp.com/index.asp>

ROR
<https://ror.org/049zrh188>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Shanghai Sixth People's Hospital (China)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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