

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

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

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## Additional identifiers

## 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 SpO<sub>2</sub>, 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 SpO<sub>2</sub> 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. PaCO<sub>2</sub>

## **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?
<a href="#">Results article</a>	results	01/09/2013		Yes	No