
**The Safety、 Efficacy and Pharmacokinetics of
Dexmedetomidine Administered Through Different Routes
in Pediatric**

October 12, 2017

Informed Consent Form

Study title : The safety 、 efficacy and pharmacokinetics of dexmedetomidine administered through different routes in pediatric

Research unit: The Second Affiliated Hospital and Yuying Children's Hospital of Wenzhou Medical University

We'll invite you to take part in a research. Before you decide whether you take part in this, please read the following information carefully. If you have any question about the research, you can ask the responsible doctor or working group members to explain it to you.

1 Background and purpose

Background Dexmedetomidine (DEX) is a highly selective α_2 adrenoreceptor agonist that provides anxiolysis, sedation, and modest analgesia with minimal respiratory depression. DEX has been reportedly used in pediatrics as a premedication, a sedation agent for use in the pediatric intensive care unit, an adjunct to inhaled anesthetic agents, and a drug for both the prophylaxis and the treatment of emergence agitation (EA) after general anesthesia. Although 10-minute DEX infusions reduce the incidence of EA in children, a rapid bolus injection, if proven to be hemodynamically acceptable, would allow a more timely and optimum administration of the drug to both treat and prevent EA. Several researches have reported that rapid IV bolus administration of DEX was clinically well tolerated, although it resulted in a transient but significant increase in systemic and pulmonary pressure and a decrease in HR. But either a small sample study, or only one dose of DEX. DEX is used frequently to prevent and treat postoperative agitation in doses of 0.25–1 $\mu\text{g}/\text{kg}$, and it is now common practice in clinical institution to administer dexmedetomidine as a rapid (less than 5 seconds) IV bolus. We therefore designed the research to study the safety 、 efficacy and pharmacokinetics of different doses of dexmedetomidine as a rapid bolus for pediatric patients.

On the other hand, our previous study revealed that intranasal dexmedetomidine premedication can low the preoperative anxiety and postoperative EA in pediatric. The nasal delivery is non-invasive 、 comfortable and easy to accept by children. So our further research is to study the pharmacokinetics after a single dose of dexmedetomidine administered as a nasal spray in pediatric.

Purpose To evaluate The safety 、 efficacy of dexmedetomidine administered through different routes in pediatric and measure their pharmacokinetics.

2 Research methods

1、 Who can participate in the research?

(1) selective operation of inguinal hernia repair、 orthopedics operation or general surgery operation in children;

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- (2) aged 3-9 years;
 - (3) ASA I - II;
 - (4) enter the operating room by himself without parents;
 - (5) normal liver and kidney function;
 - (6) no history of anesthesia medication allergy.
- 2、 Who can't participate in the research?
- (1) allergic to dexmedetomidine, similar active ingredients or excipients;
 - (2) G-6-PD deficiency;
 - (3) a history of arrhythmia, bronchial and cardiovascular diseases, abnormal liver function and so on;
 - (4) a history of use of alpha 2 receptor agonists or antagonists.

3、 Group

A total of 187 children of three research parts will be randomly enrolled into different groups .After a single dose of DEX is administered, patients will be followed by 24h.

3 The benefits , risks, costs and compensations of participating in the research

1、 What risks will I encounter in the research?

Dexmedetomidine is used frequently to prevent and treat postoperative agitation in doses of 0.25–1μg/kg ,and it is now common practice in clinical institution to administer dexmedetomidine as a rapid (less than 5 seconds) IV bolus. Previous studies reported that fast injection resulted in a transient but significant increase or decrease in systemic pressure and a decrease in HR, but all pediatric patients clinically well tolerated, and no patients required any intervention for hemodynamic changes. We will closely monitor the vital signs of children and ensure their safety. In addition, in the second and third part of study, we need to collect blood samples six times and each time need 0.4ml,which will not cause adverse reaction to the children.

If there is any discomfort or other reaction during this period, please inform the doctor in time and the doctor will take appropriate measures according to your situation.

2、 the benefits of participating in the research

You and the society will probably benefit from this research. The benefits include helping reduce total general anesthesia medication and postoperative pain, which help you recover smoothly and make you more comfortable. And this research may help to establish new experience in the treatment of postoperative agitation in pediatric.

And you will be free to use **dexmedetomidine injection** in the operation.

3、 Do I need to pay for this study?

In the study, the medication you receive is a routine treatment, and even if you do not participate in this study, these treatments are also required, but we will make the experimental drugs free of charge as compensation. There is no charge for blood concentration testing.

4、 Can I get compensation for participating in this study?

You will be reimbursed for a certain medical fee.

4 The rights you have

You have the right to decide whether or not to take part in this research. If you can't make a decision immediately, you will have sufficient time to consider it. If necessary, you can consult with your relatives, friends and other people you trust before making a decision.

If you decide not to take part in this experiment, it will not affect your relationship with the researcher. You will not be discriminated against or retaliated. Your treatment and rights will not be affected.

If you decide to take part in this experiment, if there is no special reason, we hope you can complete the test, but you have the right to exit at any time during the test. If you decide to quit, please inform the researcher in time.

During the trial period, you can always keep abreast of the information relating to you in this experiment.

5 Privacy protection

The personal information you provided to researchers (such as name, gender, contact, questionnaire etc.), in addition to the normal need to study abroad, may also be informed of the following personnel: research funding agency staff associated with the test (arbitrator, inspector, etc.);

But anyone without your permission can not disclose your personal information to others or other institutions, in addition to researchers and administrative institutions. Any other person or unit has no right to take the initiative to contact you about the test matters, or directly provide you information about the test.

The results of this test may be published in an academic paper, but no personal information will appear in any published document.

6 Others

1、 For the purpose of your health, the researcher may withdraw you from this experiment without your consent when the following situations occur:

- Continue to participate in this experiment, may lead to your risk outweigh the benefits;
- You failed to follow the investigator's instructions and don't participate in the test according to the research program;
- Test terminated ahead of schedule.

2、 This informed consent form is in duplicate, and the investigator and you each keep one copy.

7 Compensation for damage in the research

If your injury is directly caused by participating in this test, you will not have to pay for the medical expenses that will be borne by the researcher.

8 Contact

If you have any question or emergency during this clinical study, please contact your doctor.

Inform the participant: the doctor will give you a detailed explanation, so that you can fully understand the above content and give you sufficient time to consider and decide whether to participate in the research.

During the course of the study, if we get information that may affect participants continue to participate in the test, the subjects or their legal representatives will be informed in time, if necessary, to obtain the newly signed informed consent.

The experimental program is approved by ethics committee of The Second Affiliated Hospital and Yuying Children's Hospital of Wenzhou Medical University. If you have any complaints or your rights and interests are affected during the study, you can contact with the hospital ethics committee, Tel: 0577-88002560, e-mail: feykjkey@126.com.

Informed consent page

Consent:

1、 I have read carefully and understand the relevant background information of the subjects and the study, and researchers have done a detailed explanation of the characteristics of this trial and possible adverse reactions , and given the answer to my question.

2、 I have known that if i refuse to take part in this experiment, my treatment and rights will not be affected. After knowing all the details of the subjects and considering them fully, I volunteered to take part in the research.

3、 I am willing to follow the instructions of the researcher and participate in the test according to the research project. I have the right to quit at any time during the test, but before I quit, I need to tell the researcher in time.

4、 During the experiment, I will timely inform the researchers if i have any symptoms of discomfort.

Signature of the subject :

Name	Signature	Signature Date	Contact
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Signature of subject agent/guardian:

The reason why the subject

cannot sign this page :

The relationship between

the agent/guardian and

the subject:

Name	Signature and date	Contact
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Signature of the research:

Name	Signature	Signature Date	Contact
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