



## Assent Letter to Participate (Ages 7 to 12)

### Intranasal dexmedetomidine plus ketamine for procedural sedation in children: a randomized controlled non-inferiority multicenter trial (KetoDex Trial)

*Principal Investigator: Dr. Naveen Poonai, Paediatric Emergency Physician, Children's Hospital, London Health Sciences Centre (LHSC)*

*Research Ethics Board – University of Western Ontario*

#### **Why are you here?**

You have a bone injury that needs to be repaired. Your doctor believes that you will need to be put to sleep so that you don't feel pain or remember anything. Your doctor also believes that a medicine called ketamine is the best way to put you to sleep because it works very well and is very safe in kids with injuries just like yours.

#### **Why are we doing this study?**

Usually, the medicine ketamine is given through a small plastic straw in your arm. However, this is a science study and the doctors want to see if giving a different medicine by a spray in your nose is just as good as giving ketamine through the small plastic straw in your arm. The different medicine is a combination and this is called KetoDex. We need to see how sleepy the medicine makes you so we will be making a video of you during the science study. We will not share the video with anyone else but the science team. This may help us to learn a better way to help other kids with an injury like yours.

#### **What will happen to you?**

We would like to give you medicine to put you to sleep through a spray in your nose and a small plastic straw in your arm. Your mom, dad, or guardian will be asked to stay right beside you until you fall asleep. When you wake up, your bone will be fixed. After your bone is fixed, your mom, dad, or guardian will help you answer a few questions about how you felt.

#### **Will it hurt?**

When the nurses place the small plastic straw in your arm, it will hurt for a few minutes and then the pain will quickly go away. The medicine sprayed in your nose will not hurt but may feel a little funny.

Initials: \_\_\_\_\_

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**Do you have to be in this study?**

You do not have to be in this study if you don't want to. No one will be upset with you if you do not want to do this.

**Who you should contact if you have questions?**

You can ask questions at any time now or later. If you have any questions, please talk to anyone on the research team, your family or the doctor or nurse who is taking care of you.

You can also contact:

- **Dr. Naveen Poonai** at the Children's Hospital, London Health Sciences Centre at **(519) 685-8500 x 71735 - Naveen.Poonai@lhsc.on.ca**  
OR
- **Kamary Coriolano** Children's Hospital, London Health Sciences Centre at **(519) 685-8500 x 56174 - Kamary.CoriolanoDaSilva@lhsc.on.ca**
- The Office of Human Research Ethics (519) 661-3036, 1-844-720-9816,  
email:[ethics@uwo.ca](mailto:ethics@uwo.ca).

If you have any questions about your rights as a research participant or the conduct of this study, you may contact the Patient Relations Office at LHSC at (519) 685- 8500 ext. 52036 or access the online form at: <https://apps.lhsc.on.ca/?q=forms/patient-relations-contactform>.

**Assent Form**

Research Ethics Board – University of Western Ontario

**Intranasal dexmedetomidine plus ketamine for procedural sedation in children: a randomized controlled non-inferiority multicenter trial**

I have read this letter and I want to participate in this study.

\_\_\_\_\_  
Child Name (Printed)\_\_\_\_\_  
Child Signature\_\_\_\_\_  
Date\_\_\_\_\_  
Person Obtaining  
Assent (Printed)\_\_\_\_\_  
Signature of Person Obtaining  
Assent\_\_\_\_\_  
Date

Initials: \_\_\_\_\_

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