

**Boston Children's Hospital
Harvard Medical School**



Clinical Research Study

For patients scheduled for a
magnetic resonance imaging
(MRI) scan at Boston Children's
Hospital

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<http://carppo.tch.harvard.edu/>

A Pilot Study of Dexmedetomidine-Propofol in Children Undergoing Magnetic Resonance Imaging

What is this study about?

Providing, safe and effective care is the number one priority at Boston Children's Hospital. That is why the Anesthesia Department would like to do a research study to learn more about sedation in children who are having MRI scans.

Dexmedetomidine and Propofol are Food and Drug Administration (FDA) approved sedatives that are routinely used to help children sleep during procedures like MRI scans. However, Dexmedetomidine is only currently approved for sedation in adults.

Research on some anesthetic medications, including Propofol, in neonatal monkeys has suggested that some brain cells may be damaged if these medicines are given in large doses and on a frequent basis. There is also evidence to suggest that Dexmedetomidine may not have the same effect on brain cells however, Dexmedetomidine alone may not help children sleep deeply enough to complete an MRI scan.

We would like to find out if by giving Dexmedetomidine with Propofol, we may be able to reduce the amount of Propofol that is given to children.

To do this, we would like to enroll children between the ages of 1 and 12 years of age, who are having an MRI scan at Boston Children's Hospital into this research study.

Members of the research team will record how much Dexmedetomidine and Propofol your child needs, any interruptions to the

scan, vital signs, length of time participants are asleep, the length of time it takes to complete the MRI scan, and the length of time it takes participants to be able to leave the hospital after the scan is over. If the participant experiences any side effects of the drugs, that will also be recorded.

What will I be asked to do?

You will be asked to give permission for the anesthesiologist caring for your child to give a specific combination of Dexmedetomidine and Propofol during their MRI scan. This specific combination includes:

- Dexmedetomidine in a single dose based on your child's weight (1mcg/kg)
- Propofol in a single dose based on your child's weight (2-3mg/kg)
- An infusion of propofol based on your child's weight (100mcg/kg/min)

You will also be asked to give the research team permission to record information from your child's medical record, and to observe your child's care when you come to Boston Children's Hospital for their MRI Scan.

It is important to note that regardless of whether or not your child participates in this study, your child will receive anesthesia for their MRI procedure, which may be either or both of these medications. Being in this study means you agree beforehand to get a combination of dexmedetomidine and propofol at specific doses, rather than having the anesthesiologist decide what to give you at the start of your procedure.

Who is conducting this research study?

Dr. Joseph Cravero and his research colleagues in the Department of Anesthesia are conducting the study.

How do I learn more about the research?

Before your child's MRI scan, a member of our research team will call to tell you more about the study and to answer questions you may have about the study. We also invite you to view an informational slideshow about the study at:

<http://carppo.tch.harvard.edu/>

If you have any immediate questions, or if you would not like us to contact you further, please contact Jocelyn Booth. Your participation in this study is completely voluntary. You/your child may change your mind at any time and withdraw. All of your research data will be kept confidential as required by law.

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