Clinical Study Results

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study medication works, how it works, and if it is safe to prescribe to patients. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: Pfizer Inc.

Medicine(s) Studied: Precedex™ (Dexmedetomidine [DEX])

Protocol Number: C0801039

Dates of Study: 18 February 2020 to 30 November 2021

Title of this Study: Safety and Efficacy of Dexmedetomidine (DEX) for Sedation in Children Aged Between 1 Month and Up to 17 Years Undergoing an MRI Scan

[A Phase 3/4 Randomized, Double-Blind, Dose-Ranging Study of the Safety and Efficacy of Dexmedetomidine (DEX) Used With Propofol (PRO) as Needed for Procedural Sedation of Pediatric Subjects ≥1 Month to <17 Years of age Undergoing MRI Scans]

Date(s) of this Report: 07 April 2022

– Thank You –

If you or your child participated in this study, Pfizer, the Sponsor, would like to thank you both for your participation.

This summary will describe the study results. If you have any questions about the study or the results, please contact the doctor or staff at your study site.

Why was this study done?

What is MRI?

MRI stands for Magnetic Resonance Imaging, and it is a scanning machine that uses strong magnetic fields and radio waves to look inside the body. To do this, the patient needs to lie very still on a bed that is moved inside the scanner. The scanner looks a bit like a large metal tube and the magnets inside this will slowly move around the patient while the scan takes place. This means MRI scanners can make lots of noise and sometimes it can be difficult for children to stay still. If a patient moves during the MRI, then the scan may need to be repeated.

Sometimes special drugs called sedatives are given during the MRI that make the patient feel calm and drowsy. This means they are less likely to move during the MRI. One drug that can be given is propofol and this is often used as a general anesthesia for operations. The term "general anesthesia" includes medications that put you in a sleep-like state before surgery or other medical procedures.

What is dexmedetomidine?

Dexmedetomidine or DEX is a medicine that is given as an injection to adults and children in hospital. DEX is not approved for use in children who need tests like an MRI. DEX is also known as Precedex™.

What was the purpose of this study?

The purpose of this study was to see if DEX could be used to help children feel calm and drowsy and so remain still during the MRI. In this study, the researchers looked to see what would happen with 3 different doses of DEX (low, middle, and high dose) and if DEX could be given by itself without also needing propofol.

Researchers wanted to know:

Did participants taking DEX have less need for propofol during the MRI to help them remain still?

What happened during the study?

How was the study done?

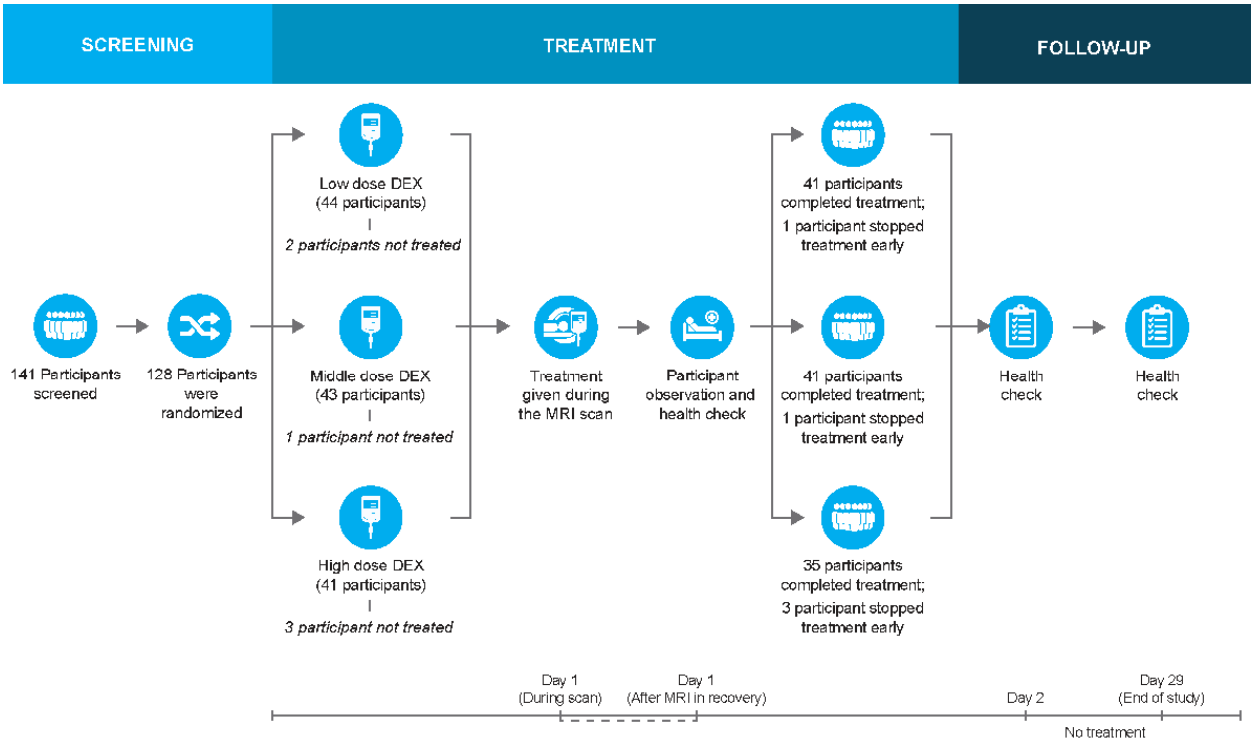
Researchers tested 3 different doses of DEX (low, middle, and high dose) on a group of study participants to find out if this treatment made participants feel calm and drowsy and so better able to remain still during the MRI. DEX is given as an injection into a blood vessel in the body during the MRI.

Researchers then compared the results of study participants given high dose DEX to the results of study participants given low dose DEX. They did this to see how many participants taking these doses of DEX did not need propofol.

After the MRI, participants were checked regularly in a recovery area until they met criteria that indicated they were ready to leave. Participants were then contacted to check on their health the following day and after about a month.

The study participants and researchers did not know who received the low, middle, or high dose DEX. This is known as a "blinded" study. Study participants were assigned to each dose of DEX by chance alone, like flipping a coin.

The following figure shows what happened in this study.



Where did this study take place?

The Sponsor ran this study at 22 locations in the US and Japan.

When did this study take place?

It began 18 February 2020 and ended 30 November 2021.

Who participated in this study?

The study included participants who needed sedation during an MRI.

- A total of 63 boys participated
- A total of 59 girls participated
- All participants were between the ages of 2 months and just over 15 years

Participants were to be treated with DEX during the MRI on Day 1. Of the 122 participants who began treatment with DEX, 117 completed treatment, and all 122 participants finished the study.

Five (5) participants stopped treatment with DEX, including 3 participants for medical reasons during the MRI (1 participant with low dose DEX, 1 participant with middle dose DEX, and 1 participant with high dose DEX) and 2 participants for other reasons (both with high dose DEX).

How long did the study last?

Each study participant was in the study for about 1 month. The entire study took almost 22 months to complete.

The study ended in November 2021. The Sponsor reviewed all information collected and created a report of the results. This is a summary of that report.

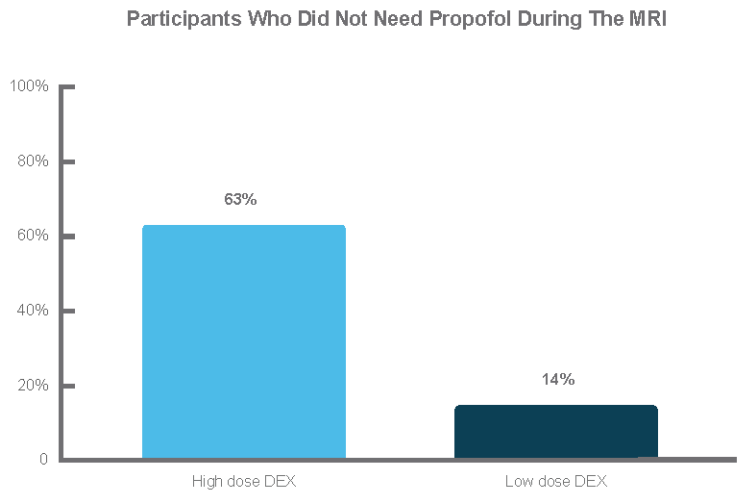
What were the results of the study?

Did participants taking DEX have less need for propofol during MRI to help them remain still?

The researchers wanted to see how many participants given DEX without propofol to make them calm and drowsy remained still during the MRI. They did this by comparing the number of participants who did not need propofol in the high dose DEX group with the number of participants who did not need propofol in the low dose DEX group.

Did high dose DEX help participants to feel calm and drowsy and so better able to remain still during the MRI compared to participants given low dose DEX?

Twenty-four (24) out of 38 (63%) participants who received the high dose DEX did not need propofol compared to about 6 out of 42 (14%) participants who received the low dose DEX.



Based on these results, the researchers have decided that the results are not likely the result of chance. The study medication may help participants feel calm and drowsy and remain still during MRI without the need of propofol.

This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies may have different results.

What medical problems did participants have during the study?

The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could also have been caused by a study treatment or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many treatment groups in many studies, doctors try to understand what effects a study medication might have on a participant.

There were 113 out of 122 (93%) participants in this study who had at least 1 medical problem. Most of these medical problems were mild. A total of 3 participants stopped treatment because of medical problems. The most common medical problems – those reported by 5% or more participants – are described below.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists medical problems that were commonly reported during the study. All medical problems reported by 5% or more participants are listed.
- The **2nd** column tells how many of the 42 participants given low dose DEX reported each medical problem. Next to this number is the percentage of the 42 participants given low dose DEX who reported the medical problem.
- The **3rd** column tells how many of the 42 participants given middle dose DEX reported each medical problem. Next to this number is the percentage of the 42 participants given the middle dose of DEX who reported the medical problem.
- The **4th** column tells how many of the 38 participants given high dose DEX reported each medical problem. Next to this number is the percentage of the 38 participants given high dose DEX who reported the medical problem.
- Using these instructions, you can see that 24 out of the 42 (57%) participants given low dose DEX and 24 out of the 42 (57%) given the middle dose of DEX had a heartbeat that was slower than normal compared to 27 out of the 38 (71%) participants given high dose DEX who had a heartbeat that was slower than normal.

Table 1. Commonly reported medical problems by study participants			
Medical Problem	**Low Dose DEX (42 Participants)**	**Middle Dose DEX (42 Participants)**	**High Dose DEX (38 Participants)**
Heartbeat slower than normal	24 out of 42 participants (57%)	24 out of 42 participants (57%)	27 out of 38 participants (71%)
Heartbeat faster than normal	3 out of 42 participants (7%)	1 out of 42 participants (2%)	1 out of 38 participants (3%)
Slow breathing rate	33 out of 42 participants (79%)	27 out of 42 participants (64%)	22 out of 38 participants (58%)
Low levels of oxygen in blood	6 out of 42 participants (14%)	3 out of 42 participants (7%)	1 out of 38 participants (3%)
High blood pressure	11 out of 42 participants (26%)	17 out of 42 participants (40%)	18 out of 38 participants (47%)
High blood pressure - the top number only	1 out of 42 participants (2%)	5 out of 42 participants (12%)	3 out of 38 participants (8%)
High blood pressure - the bottom number only	3 out of 42 participants (7%)	3 out of 42 participants (7%)	4 out of 38 participants (11%)
Low blood pressure	13 out of 42 participants (31%)	11 out of 42 participants (26%)	6 out of 38 participants (16%)

Did study participants have any serious medical problems?

A medical problem is considered "serious" when it is life-threatening, needs hospital care, or causes lasting problems. Important medical events are also considered serious.

Three (3) participants (2%, or 3 out of 122 participants) had serious medical problems.

- One (1) participant given high dose DEX had high blood pressure during the MRI, treatment with DEX was stopped, and the participant recovered. This event was thought related to DEX and possibly other medicines the participant was taking.
- One (1) participant given low dose DEX had surgery on Day 24 after the MRI and developed breathing difficulties and blood poisoning on Day 30. This event was not thought related to DEX and the participant recovered.
- One (1) participant given low dose DEX had a seizure on Days 2 and 21 after the MRI. This participant had previously experienced seizures and the events were not thought related to DEX and the participant recovered.

No participants died during the study.

Where can I learn more about this study?

If you have questions about the results of your study, please speak with the doctor or staff at your study site.

For more details on your study protocol, please visit:

www.clinicaltrials.gov	Use the study identifier NCT04237792
www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number C0801039

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients.

Again, if your or your child participated in this study, **thank you** for volunteering. We do research to try to find the best ways to help patients, and you helped us to do that!