

Optimizing Pain Treatment In Children on Mechanical Ventilation Study (OPTICOM)

IRB #: _____

1 Why are we doing this study?

- We want to learn how to best treat pain in children on **mechanical ventilators (MV)**.
- Right now, doctors give all kids on MV strong pain medicines called **opioids**.
- The goal of this study is to see if adding other pain medicines (like **acetaminophen** -- you might know it as Tylenol, and **ketorolac** -- also called Toradol) can help manage pain and decrease the amount of opioid needed.

2 Where is this study taking place?



- We are inviting participants at ~15 hospitals in the US to join this study.
- Our goal is to enroll 644 patients between 2 months and 17 years old.

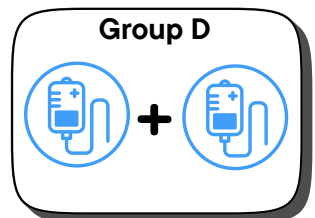
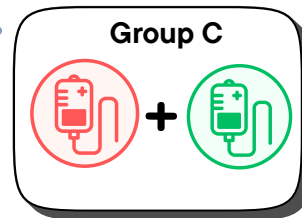
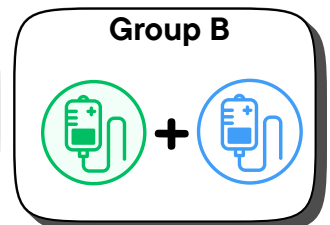
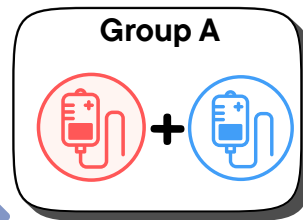
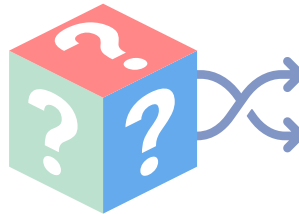
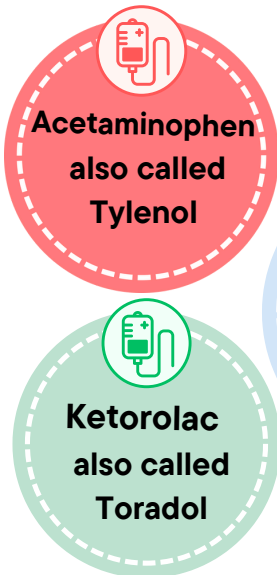


3 What is involved in participating in this study?

Your child will receive a mix of the medicines below:

A computer will randomly choose what mix of medications your child will receive.

Your child will be placed in **1 of 4 treatment groups**. Only the pharmacist who prepares the medicine will know which group of medicine your child will receive.



How long is participation?



- Your child will be in the study for up to 5 days or until they are taken off the ventilator, whichever happens first.

What will be collected?

- Information will be collected from your child's medical records so we can see how they are doing during their hospital stay.
- If not performed as part of routine care, blood samples may be collected from your child before and after the study treatment.
- We will also ask you (the parent/guardian) to complete a set of surveys about your child after enrollment and again when your child is discharged.
- Your child's information will be kept securely and only accessed by authorized personnel. Shared study results will not have any of your child's personal information.



Anything else?

THAT'S IT!

- Your child will receive the same medical care, including any necessary pain medications prescribed by their doctors, whether or not they participate in this study. **Their health and well-being remain the top priority.**



To learn more about this study, please speak with your child's doctor.