

**N-of-1 Trials in Children with Hypertension (NICHE)
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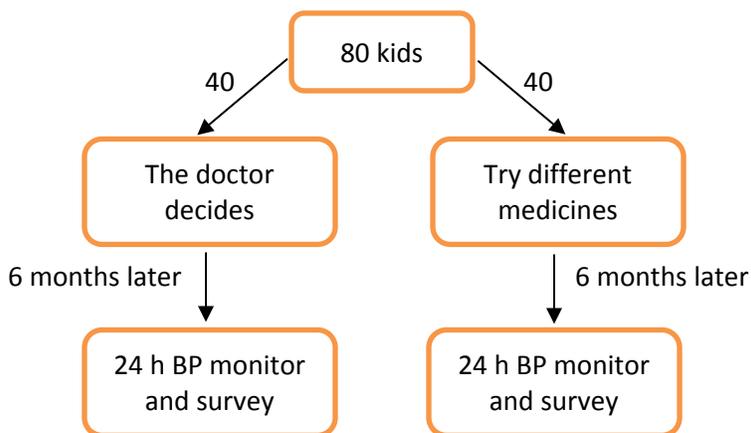
The purpose of the NICHE study is to improve the care we provide at the UTHealth Pediatric Hypertension clinic by comparing two different methods of choosing medicine for treating high blood pressure in children. Your child’s doctor has decided your child needs to take a blood pressure medicine. There are many different blood pressure medicines that are safe, effective, and commonly used in children with high blood pressure. Each child is unique and might respond differently to various blood pressure medicines. We do not have a way to predict which one will be best for your child.

Usually, the doctor decides which medicine they want to prescribe to your child. The doctor will bring you back for follow-up visits to monitor your child’s blood pressure and may change the blood pressure medicine if he/she thinks another one may be better.

This study is testing a new method, called the NICHE method. Instead of the doctor deciding which medicine to prescribe, your child will start out by trying two different blood pressure medicines, one at a time. After the medicine is taken for 2 weeks, we will check to see how well it worked and then switch to the next one. The order of the medicines, the number of times each medicine is tried and the dose of the medicines are decided by the NICHE study rules. The children who are assigned to the NICHE study method will do the 24 hour blood pressure monitoring once every two weeks for two to four months. At the end, we will decide together which medicine your child responded to the best. There are no added costs or planned extra visits.

Children who are taking part in the NICHE study will be randomly assigned (like flipping a coin) to the usual way of the doctor choosing the blood pressure medicine or the NICHE method of trying different medicines. After 6 months, all of the children who take part will do a 24 hour blood pressure monitoring so we can compare how well the blood pressure is controlled with the two methods, and we will ask you to complete a survey about the care your child received.

If at any point, for any reason, you or your child doesn’t want to continue in the study you can stop and your doctor will continue to treat your child’s blood pressure.



We do not think there are any physical risks risks to taking part in the NICHE study because the blood pressure medicines that are being used in the NICHE study are the same medicines that your child might have been prescribed outside of the NICHE study.

There is a risk of loss of confidentiality. Your child's privacy is very important to us. Your doctors will collect details about your child's blood pressure treatment from the medical record and the study doctors will have access to that information and your child's medical record number for tracking purposes. The study doctors will make every effort to protect the information they collect. In addition to the study team, other UTHealth employees may look your child's research and medical records and will see personal identifiers if they audit the NICHE study. You may revoke our permission to access your child's information by contacting us, but we may not be able to remove your child's information from the study if we have already used it. Your child's treatment is not conditioned in any way on your agreeing to give your child's information to the research team. Your child will not be personally identified in any reports or publications of the study results.

A description of this clinical trial will be publicly available on <http://www.ClinicalTrials.gov>.

Dr. Samuel can be contacted directly using the information below with any questions, comments or concerns.