



LOMA LINDA UNIVERSITY CHILDREN'S HOSPITAL

Informed Consent / Parental Permission

11234 Anderson Street
Loma Linda, California 92354
(909) 825-KIDS (5437)

Title: Validation of the standard optimal volume for measuring intra-abdominal pressure.

The following informs you of a research study that you are invited to take part in. Attached is the California Subjects Bill of Rights. It explains your rights as a research participant. You can make the choice to participate or not.

Why Is This Study Being Done?

You are invited to take part in this study because your child has a tube in his/her abdomen. High pressure in the abdomen may happen in very sick children. It is dangerous because it increases the chances of dying in people who have it. Your child most likely does not have high abdominal pressure. The purpose of this study is to test a way for measuring the pressure inside the abdomen using a tube in the bladder. This way of measuring pressure in the abdomen is already used in children and adults that are likely to develop high pressure in the abdomen. It involves putting a tube in the bladder through the hole that urine comes out of and putting a small amount of liquid in the bladder through this tube. A small device that measures pressure will be attached to the end of the tube. This will let pressure in the abdomen be measured through the bladder. Because the bladder normally sits in the abdominal space, it transmits pressure from the entire abdomen. Putting a tube directly in the abdominal space and attaching the device that measures pressure to the end of this tube can also measure pressure in the abdomen. The difference between these two ways is that the bladder way is not directly in the abdominal space but in the bladder therefore it is an indirect method. The other method measures pressures directly in the abdominal space. To use the bladder way of measuring pressure a small amount of liquid needs to be put in the bladder. If the amount of liquid put in the bladder is too much or too little it can make the pressures read incorrectly. A recent research study showed that using 3ml (less than a teaspoon) of liquid in the bladder gave accurate abdominal pressure readings. This research study is being done to test whether using 3ml as the volume in the bladder in children under many different circumstances would give accurate pressures. The study will compare pressures taken by the bladder method with pressures taken by directly measuring pressure in the abdomen.

What is involved in the study?

Each patient will have a urine tube put into his or her bladder if one is not already in place, then a pressure device will be connected to the end of the tube for measuring pressure. Pressures measured through the urine tube and through the tube in the abdomen will be taken at the same time. How often the pressures will be taken depends on the reason your child has his/her abdominal tube:

a.) Children with abdomen tubes for dialysis:

If your child has the abdomen tube because he/she is regularly on or will be having dialysis, then pressure measured using the abdomen tube will be taken every five minutes for two dialysis cycles. It will take about 2-4 hours depending on how long the dwell and drain times are. There are two parts to a dialysis cycle, a dwell time, this is when a set volume of liquid is drained into the abdomen and left there for several minutes and the drain time is when that volume is

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allowed to drain out of the abdomen over several minutes. How long the drain and dwell times last were determined by your managing physician or nephrologists.

b.) Children with abdomen tubes for draining unwanted fluid:

If your child has the abdomen tube to remove unwanted fluid in the abdomen then pressure measurements will be taken every 2 hours for 24 hours.

Procedures that are part of your regular care and may be done even if you do not participate in the study include:

- a. Placement of the abdomen tube.
- b. Placement of the urine tube.

Standard procedures being done because you are in the study:

- a. Placement of a urine tube (if subject does not already have one in place).
- b. Attachment of pressure transducers (the device for measuring pressure) to the abdomen tube and urine tube.
- c. Placement of 3ml of fluid into the bladder for pressure measurements.
- d. Pressure measurement through the abdomen tube.

Participation in the study will last 2-4 hours if your child has the abdomen tube for dialysis. For patients with a tube because of unwanted fluid, the study will last 24 hours

The researcher may decide to take your child out of the study if it is in the best medical interest of your child, funding is stopped or it is determined that the research study cannot be performed on your child.

What are the Risks of the study?

Participants in the study are at risk for the following side effects:

- a. Pain or discomfort on insertion of the urine tube -- very likely
- b. Urinary tract infection – very unlikely
- c. Infection in the abdominal space – very unlikely

The committee at Loma Linda University that reviews human studies has determined that participating in this study exposes you to a minor increase over minimal risk. Other side effects may occur that we cannot predict.

Are there benefits to taking part in this study?

There may or may not be direct medical benefit to you. We hope the information learned from this study will benefit other patients at risk for high pressure in the abdomen in the future.

What about confidentiality?

Efforts will be made to keep your personal information confidential at the same standards as the confidentiality held with your medical records. We cannot guarantee absolute confidentiality.

What are the costs?

There is no cost to you for participating in this study. You and your insurance company are responsible for the costs related to routine medical treatment and/or hospitalization. If in doubt about reimbursement, you should contact your third-party payor.

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What if I am injured as a result of participating in this study?

Precautions will be taken to minimize risks associated with the study. In the case of injury or illness resulting from this study, emergency medical treatment is available but will be provided at the usual charge. No funds have been set aside to compensate you in the event of injury.

What are my rights as a participant?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not affect your medical care or relationship with the hospital. However if you decide to stop participating in the study we encourage you to talk to the researcher and your regular doctor first.

Whom do I call if I have concerns about my rights as a research participant?

If you wish to contact an impartial third part not associated with this study regarding any complaint, you may contact the **Office of Patient Relations at Loma Linda University Medical Center, Loma Linda, California 92354, or call 909-558-4647** for information and assistance.

Informed Consent statement:

"I have read the contents of the consent form and have listened to the verbal explanation given by the investigator. My questions concerning this study have been answered to my satisfaction. I have received a copy of the California Experimental Subject's Bill of Rights and have had these rights explained to me. I hereby give voluntary consent to participate or have my child participate in this study. Signing this consent document does not waive my rights nor does it release the investigators, institution or sponsors from their responsibilities. I may call the investigator, J. Chiaka Ejike, MD at (909) 558-4357 if I have additional questions or concerns. I have been given a copy of this consent form."

Subject is unable to sign because _____ Minor _____ Sedated _____

Signature of minor (age 13 –17yrs) _____ Date _____

Signature of parent/guardian _____ Relationship _____ Date _____

"I the study investigator attest that the requirements for informed consent from the medical research project described in this form have been satisfied – that the participant has been provided with a copy of the California Experimental Subject's Bill of Rights, that I have discussed the research project with the participant and explained to him or her in nontechnical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered."

Date: _____ Time: _____ A.M./P.M.

Signature: _____
(Study Doctor)

As the primary physician responsible for the care of the patient, I indicate having knowledge of this research participation."

Signature of Primary Physician _____

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