

CSF OPENING PRESSURE STUDY

This study is prospectively evaluating the CSF opening pressure in children in hopes of establishing authoritative norms for each age group. If a child is undergoing a Lumbar Puncture (LP) as part of their routine care, we would like to document their opening pressure, indication for LP, depth of sedation, and level of agitation during measurement of the opening pressure.

Does the patient have ANY Exclusion Criteria (check any that apply)?

- Age <1 year or >18 years
- LP **NOT** performed in the lateral recumbent position
- Indwelling ventricular shunt or lumbar drain
- Current or past diagnosis of a CNS tumor
- Active oncologic (Non-CNS) disease undergoing treatment
- Hypotension requiring hemodynamic support with pressors
- Medically unstable patient in which additional time required to obtain the opening pressure would compromise patient management or safety
- Patient being evaluated for head trauma during admission
- Patients with a medical condition where an LP would be contraindicated

1) Does the patient have any of the above EXCLUSION criteria?

YES – Please list the *patient's initials* and *age* below:

Initials (first/middle/last) _____

Age (years) _____

Today's Date (mm/dd/yy) _____

Now return this paperwork to study box. No further data should be collected.

NO – **They are eligible to be consented for the study.** Please continue to next page, obtain verbal consent (see page 2) and then complete page 3 and place in study box.

Verbal Consent for CSF Opening Pressure Study

PLEASE READ THE FOLLOWING TO THE PARENTS AND CHILD (IF AGE APPROPRIATE) PRIOR TO UNDERGOING LUMBAR PUNCTURE.

“When you/your child are undergoing the lumbar puncture (spinal tap), we would like to collect information, as part of a research study. This study is being done here at CHOP and we hope to learn how to better interpret the results from the lumbar puncture. This improved understanding may increase our ability to diagnose brain diseases. If you agree, we would like to include the results from your/your child’s lumbar puncture (spinal tap) in our research project. Your/your child’s current and future medical care at CHOP will not be affected if you/your child decide not to take part in the study. Your/your child’s participation will **NOT** involve any additional testing or procedures. We are **only** asking for permission to record the results of tests that your/your child’s doctor has ordered for you/your child during their stay and include them in our study. A member of the CHOP research team who is not involved in your/your child’s care will also collect information about your/your child’s medical condition and current medications you/your child is taking during their stay. A member of the study team may call you/your child at home after you/your child have been discharged to discuss your/your child’s diagnosis and whether you/your child have needed further medical care. All information gathered as part of this study will be kept confidential, as required by law. If any publication results from this study, you/your child will not be identified by name. Only individuals involved in the study will have access to your/your child’s information. You/your child will **NOT** be paid for participating in the study. You/your child or your/your child’s insurance company will **NOT** be charged for participating in the study. Do you have any questions?”

Did the parent agree (circle one)? Yes No

“I certify that this study and the procedures involved have been explained to [*insert subject’s name*] in terms he/she could understand and that he/she freely consented/assented to take part in this study”

Signature of person obtaining consent/assent

Date

IRB APPROVAL DATE 11/9/07
EXPIRATION DATE 9/18/10

Name: _____

MRN: _____

Date of LP: _____

1) Indication for LP (check one):

- suspected infection
- concern for increased ICP
- Other _____

2) LP needle size:

- | <u>Gauge</u> | <u>Length</u> |
|-----------------------------|-------------------------------------|
| <input type="checkbox"/> 18 | <input type="checkbox"/> 1.5 inches |
| <input type="checkbox"/> 20 | <input type="checkbox"/> 2.5 inches |
| <input type="checkbox"/> 22 | <input type="checkbox"/> 3.5 inches |
| <input type="checkbox"/> 24 | <input type="checkbox"/> 5 inches |

3) Was the spinal needle inserted in a Lumbar interspace with the bevel facing up towards the ceiling?

- YES
- NO

4) Opening Pressure (highest resting level of CSF sustained for at least 10 seconds)

- a) Flexed Lateral Recumbent Position: _____(cm H2O)
- b) Extended Position: _____ (cm H2O) (If applicable)

5) Was there adequate CSF flow to obtain the opening pressure?

- YES
- NO

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6) Depth of Sedation (Categories based on ASA and AAP guidelines)

Check One of the Following Categories

- No Sedation used
- Minimal Sedation (Anxiolysis) A drug-induced state during which patients respond normally to verbal commands, although cognitive function and coordination may be impaired.
- Moderate Sedation (Conscious Sedation) A drug-induced depression of consciousness during which patients respond purposefully** to verbal commands, either alone or accompanied by light tactile stimulation.
- Deep Sedation A drug-induced depression of consciousness during which patients CANNOT be easily aroused but respond purposefully** following repeated or painful stimulation.

****Reflex withdrawal from a painful stimulus is not considered a purposeful response**

7) Agitation Score

Did the patient have any objective evidence of SUSTAINED discomfort or anxiety (i.e., crying, verbal reports of pain, movement, facial grimacing, elevated heart rate/blood pressure beyond baseline levels) occurring during the EXACT moment when the Opening Pressure was determined? Check one:

- YES (list): _____
- NO

8) Name of Person Performing LP: _____

9) Level of Training: Resident (year)_____ Fellow Attending

STOP

Please Return the
Completed Form to the
Study Box

*****Please remove the last page entitled “Lumbar Puncture – Opening Pressure INFORMATION SHEET” and give it to the Parent/Patient*****

Lumbar Puncture - Opening Pressure INFORMATION SHEET

This handout provides additional information about the research study "Prospective Evaluation of CSF Opening Pressure in Children Undergoing Lumbar Puncture".

The use of "you" in this form refers to either you or your child.

What is a Lumbar Puncture?

You are about to have a lumbar puncture (also known as a "Spinal Tap"). This is a common procedure that involves inserting a needle into the spinal canal and removing some of the fluid that bathes the spinal cord and brain. This fluid is called cerebrospinal fluid (CSF) and is sent to the laboratory to look for signs of infection and inflammation.

What is an Opening Pressure?

Normally, the CSF is under a small amount of pressure in order to keep the brain from hitting against the skull. The opening pressure in children undergoing lumbar puncture is a measure of the pressure that this fluid is under. The opening pressure is measured by attaching a small tube called a manometer to the spinal needle.

What is the Purpose of this Study?

Measuring opening pressure provides useful information for diagnosis and management of brain and spinal cord diseases. By collecting information from your lumbar puncture, opening pressure, and other tests, we hope to better understand what are the "normal" and "abnormal" values for an opening pressure. This may also improve our ability to identify brain diseases.

What will be Done During the Study?

A member of the Children's Hospital research team who is not involved in your care will collect information about your lumbar puncture, opening pressure, medical condition and current medications taken during your stay. A member of the study team may call you at home after you have been discharged to discuss your diagnosis and whether you have needed further medical care.

Risks of Participating in this Study

There are no added risks involved in participating in this study. Your participation will **NOT** involve any additional testing or procedures. We are **only** asking for permission to look at and collect the test results that your doctor has ordered for you.

Are There any Benefits to Taking Part in this Study?

There is no direct benefit to you from participating in this study. If you participate in this study, you may help us to better understand what a "normal" opening pressure is for children of different ages.

If you have questions about the study, call the study doctor, Dr. Robert Avery, at 215-590-1719. You may also talk to your own doctor if you have questions or concerns.