Analysis of Cerebrospinal Fluid Dynamics in Patients with Normal Pressure Hydrocephalus Using Magnetic Resonance Imaging

NCT Number

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1. Purpose of the Study

The purpose of this study is to evaluate whether cerebrospinal fluid (CSF) flow dynamics measured by phase-contrast magnetic resonance imaging (MRI) can assist in the diagnosis and prognostic assessment of normal pressure hydrocephalus (NPH), and to determine how changes in CSF flow before and after CSF drainage are associated with clinical improvement.

2. Background

Normal pressure hydrocephalus (NPH) is a neurological disorder characterized by enlargement of the cerebral ventricles due to an abnormal accumulation of CSF, leading to gait disturbance, cognitive impairment, and urinary dysfunction. There is currently no proven effective pharmacological therapy. Standard treatment involves repeated CSF drainage procedures or surgical shunting with ventriculoperitoneal shunt placement. However, these procedures have a relatively high rate of failure or revision due to complications such as infection or shunt malfunction.

As the underlying cause of NPH remains unclear and treatment outcomes vary among patients, early and accurate identification of appropriate candidates is critical. Patients often experience gradual deterioration in walking ability, cognitive function, and urinary control, which may lead to falls, functional decline, dependency, and increased morbidity. Therefore, early diagnosis and proper patient selection are crucial for better clinical outcomes.

Advanced imaging modalities have recently been introduced to improve diagnostic and prognostic accuracy in NPH. Among them, phase-contrast MRI is increasingly recognized for its ability to quantitatively and qualitatively assess CSF flow dynamics. This study aims to analyze changes in CSF flow before and after CSF drainage using phase-contrast MRI and to investigate their relationship with clinical improvement.

3. Expected Study Duration and Number of Participants

This study will be conducted at two medical centers (Chungnam National University Hospital and Chungnam National University Sejong Hospital) and plans to enroll a total of

22 participants. The overall study duration is estimated to be 36 months.

Your personal participation will require up to three (3) days, including one hospitalization period (approximately 3 days) and one visit to an external imaging facility (Korea Basic Science Institute).

4. Study Procedures

This study will examine changes in CSF flow before and after CSF drainage using phase-contrast MRI. The CSF drainage procedure performed in this study is a standard clinical treatment for NPH. The procedure is performed in the lateral decubitus position, with a needle inserted between the L4–L5 interspace to remove CSF (approximately 50 mL). The procedure typically takes about one hour.

Before and after the CSF drainage procedure, you will undergo the following assessments (each set of assessments repeated twice):

1) Cognitive testing: MMSE (Mini-Mental State Examination) and FAB (Frontal Assessment Battery) (approximately 15 minutes)

2) Gait evaluation (approximately 10 minutes)

- 10-meter walk test
- 3-meter Timed Up and Go (TUG) test
- 3-meter TUG with cognitive dual-tasking (animal naming)

3) Quantitative gait analysis (approximately 10 minutes)

4) Imaging tests:

- Phase-contrast MRI scan (approximately 25 minutes)
- Functional MRI (fMRI) scan (approximately 15 minutes)

Eligible participants are adults aged 55 to 80 years diagnosed with NPH. Participation is voluntary and will proceed only after written informed consent is obtained. Participation is not permitted if inclusion/exclusion criteria are not met during screening.

5. Alternative Treatment Options

Whether or not you decide to participate in this study, you may continue to receive the standard treatments available for NPH, including CSF drainage and ventriculoperitoneal shunt surgery.

6. Voluntary Participation and Right to Withdraw

Your participation in this study is entirely voluntary. You may decide not to participate or you may withdraw from the study at any time without any penalty or loss of benefits to which you are otherwise entitled. If you choose not to participate, or if you later decide to withdraw, your medical care and relationship with your physician will not be affected in any way. Your decision will not impact your right to receive standard medical treatment now or in the future.

7. Potential Benefits

There is no guarantee that you will personally benefit from participation in this study. However, the CSF drainage procedure may improve gait and cognitive function in some patients with NPH. The information obtained from this research may contribute to improved treatment strategies for future patients with similar conditions.

8. Risks, Side Effects, and Possible Discomforts

Possible risks associated with participation in this study primarily relate to the CSF drainage procedure and include:

- Local bleeding or infection at the puncture site
- Irritation or injury to nearby spinal nerves, which may cause numbness or weakness in the lower limbs
- Low intracranial pressure symptoms such as headache or dizziness, which may occur after CSF removal

In addition, this study requires one visit to an external imaging facility (Korea Basic Science Institute) during your hospital stay for MRI scanning. Transportation to and from the external facility will be arranged by the research team.

9. Participant Responsibilities

As a participant in this study, you are asked to cooperate with all assessments performed before and after CSF drainage. This includes attending scheduled visits, undergoing cognitive tests, gait evaluations, and MRI examinations as described above.

10. Compensation and Study-Related Costs

You will receive travel reimbursement of 100,000 KRW for your participation. Partial reimbursement may be provided if scheduled visits are not fully completed, based on the extent of participation.

The cost of hospitalization related to the standard CSF drainage procedure will be your responsibility, as it is part of the routine treatment for NPH. However, the MRI examinations specifically associated with this research will be covered by the study. Costs unrelated to the research, such as general hospitalization fees, outpatient visits, medications, or other standard medical care expenses, will remain your responsibility.

11. Compensation for Research-Related Injury

If you experience any foreseeable or unforeseeable side effects or complications related to this research, you will receive appropriate medical treatment from the study investigator. For complications such as bleeding or infection at the puncture site, wound care or other medically indicated treatment will be provided depending on severity. In rare cases of spinal nerve irritation or injury, supportive treatment will be administered. If symptoms of low intracranial pressure occur after CSF drainage, you will be monitored and managed conservatively, as these symptoms typically improve with rest.

If any physical injury, disability, or serious incident occurs during transportation to or from the external imaging facility or during imaging procedures performed as part of this study,

compensation will be provided according to the compensation policy set forth in this research protocol.

However, compensation will not be provided in the following circumstances:

The injury is not directly related to the study

The injury results from the participant's negligence or non-compliance (e.g., using medications not reported to researchers, ignoring medical instructions, etc.)

The injury is due to progression or worsening of the participant's underlying medical condition

Expected lack of therapeutic benefit or insufficient improvement from the study procedure

Failure to follow pre-arranged study visit schedules

Injury caused by participant's own carelessness

12. Study Discontinuation and Withdrawal

Although participation is voluntary, the study investigator may withdraw you from the study if certain discontinuation criteria are met or if continued participation is deemed unsuitable for safety or scientific reasons. If you are withdrawn from the study, you may continue receiving standard medical care, including CSF drainage, as clinically indicated.

Data collected prior to withdrawal may still be used for research analysis, but no additional study-related data will be collected after your withdrawal.

13. Provision of New Information

If new information becomes available during the course of this research that may influence your willingness to continue participation, you will be informed promptly. You may then decide whether to continue or to withdraw from the study.

14. Confidentiality and Protection of Personal Information

Your personal information will be kept strictly confidential and will not be disclosed without your written permission unless required by law. Data collected in this study will not be used to personally identify you. All records will be stored securely in a locked facility and in encrypted digital format, accessible only to the principal investigator and authorized study personnel.

When information needs to be transmitted electronically or via storage devices, it will be encrypted. Any reports, publications, or presentations resulting from this study will not contain information that could identify you.

For monitoring and verification of study conduct and data accuracy, authorized personnel may review your research records within legal and ethical limits, without violating confidentiality. Those who may have access include:

Internal monitors for study oversight

The Institutional Review Board (IRB) reviewing the ethical and scientific validity of the research

By signing this consent form, you acknowledge that you have been informed of these confidentiality provisions and agree to them.

15. Contact Information

If you have any questions about this study or experience any problems during your participation, please contact:

Principal Investigator:

Name: Eungseok Oh

Phone: +82-42-280-7800

Study Coordinator:

Name: Hyunjoo Kwon

Phone: +82-42-280-7800

24-hour contact (if needed)

Address:

Chungnam National University Hospital

282 Munhwa-ro, Jung-gu, Daejeon 35015, Republic of Korea

If you have questions about your rights as a research participant or wish to discuss ethical or general concerns related to the study, please contact:

Human Research Protection Center (HRPC)

Phone: +82-42-280-6781

Email: hrpp@cnuh.co.kr

Address:

Clinical Research Ethics Center (HRPC)

2nd Floor, Biomedical Research Convergence Center

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