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

NCT Number

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Study protocol

A. Equipment Information and Management

- 7T MRI System (7T Magnetic Resonance Imaging)

Model and Manufacturer: Philips Achieva 7.0T Scanner (Philips Medical Systems, The Netherlands)

Purpose of use: Functional MRI (fMRI) acquisition

Storage/Installation site: Korea Basic Science Institute

- 3T MRI System (3T Magnetic Resonance Imaging)

Model and Manufacturer: Philips Achieva 3.0T Scanner (Philips Medical Systems, The Netherlands)

Purpose of use: Cine phase-contrast MRI acquisition

Storage/Installation site: Korea Basic Science Institute

B. Detailed Study Procedures

1) Confirmation of inclusion/exclusion criteria and obtaining written informed consent.

2) Baseline assessments (prior to CSF drainage)

3) Cognitive evaluation: MMSE and FAB (approximately 15 minutes)

4) Gait assessment: 10-meter walk test, 3-meter Timed Up and Go (TUG) test, and 3-meter TUG with cognitive dual task (animal naming), approximately 10 minutes

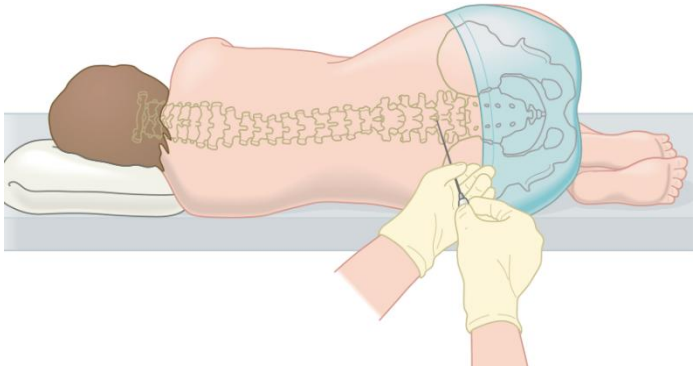
5) Quantitative gait analysis (approximately 10 minutes)

6) Pre-drainage MRI: Cine phase-contrast MRI (approx. 25 minutes) and fMRI (approx. 15 minutes)

7) CSF drainage procedure (standard of care for NPH):

8) Patient positioned in the lateral decubitus position

9) Lumbar puncture performed at L4–L5 interspace



10) Approximately 50 mL of CSF removed

11) Total procedure time: approximately 1 hour

12) Post-drainage MRI: Cine phase-contrast MRI (approx. 25 minutes) and fMRI (approx. 15 minutes)

13) Post-drainage follow-up assessments

- At 1–6 hours after drainage: repeat gait assessment and quantitative gait analysis (same as step 2), approximately 20 minutes, and repeat cognitive evaluation (same as step 2), approximately 15 minutes

- At 24 hours after drainage: repeat gait assessment and quantitative gait analysis (same as step 2), approximately 20 minutes

Statistical Analysis

Phase-contrast MRI will yield key CSF flow parameters across the region of interest, including:

1. Mean flow (ml/sec)

   (positive values: caudocranial; negative values: craniocaudal)

2. Maximum diastolic velocity (cm/s)

3. Maximum systolic velocity (cm/s)

4. Volume per cardiac cycle

- Differences in CSF flow parameters before vs. after CSF drainage will be evaluated using a paired t-test (two-tailed, $p < 0.05$).
- Changes in cognitive test scores and gait parameters before vs. after drainage will also be analyzed using a paired t-test.
- The relationship between changes in CSF flow metrics and changes in gait performance will be assessed using one-way ANOVA, followed by Tukey's post hoc test for pairwise comparisons.

For the fMRI data:

- Brain activation maps will be analyzed using statistical parametric mapping (SPM).
- Changes in network-level connectivity during gait-related tasks will be examined using Dynamic Causal Modelling (DCM).
- The pre- vs. post-drainage differences in brain activation and connectivity measures will be tested using a paired t-test.