

# Conservative versus surgical management of idiopathic normal pressure hydrocephalus: a prospective double-blind randomized controlled trial: study protocol

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Abstr.: There is no level I evidence to indicate whether placement of a shunt is effective in the management of idiopathic normal pressure hydrocephalus (INPH), because no trial has as yet compared the placement of a shunt versus no shunt in a randomized controlled manner. We started recruiting patients into a prospective double-blind randomized controlled study aiming to provide class I evidence supporting or refuting the role of surgical management in INPH. Inclusion criterion was the diagnosis of probable INPH plus objective improvement of walking speed following 72 h of extended lumbar drainage. Patients with concomitant Alzheimer's disease or vascular dementia were excluded. All patients included in the trial were to have a shunt placed with proGAV((R)) adjustable valve. Patients were randomly assigned into two groups: group A was to have the shunt immediately adjusted to function, and group B was to have the shunt valve adjusted to the highest setting for 3 months then adjusted to function. Assessment of gait, cognitive function, and urinary symptoms were done before shunt insertion and at 3 months. Primary end point was to be an improvement in gait. Secondary end points were improvement in mental function or urinary function and incidence of complications. Final results are expected mid 2011.