Cerebrospinal Fluid Research

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Poster Presentation

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A prospective, randomised, controlled trial to evaluate the efficacy and safety of endoscopic choroid plexus coagulation with third ventriculostomy in the treatment of idiopathic normal pressure hydrocephalus [ISRCTN29863839]

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from 48th Annual Meeting of the Society for Research into Hydrocephalus and Spina Bifida
Dublin, Ireland, 23–26 June 2004
Published: 23 December 2004

Cerebrospinal Fluid Research 2004, **1**(Suppl 1):S58 doi:10.1186/1743-8454-1-S1-S58

This article is available from: http://www.cerebrospinalfluidresearch.com/content/1/S1/S58

Background

The current treatment of choice for Normal Pressure Hydrocephalus (NPH) is a CSF shunt, however, this carries significant morbidity with reported complication rates following shunt surgery averaging 38%, with a 6% rate of permanent neurological deficit or death [1]. NPH can be viewed as a slowly progressive communicating hydrocephalus. Endoscopic coagulation of the choroid plexus (CPC) has been shown to be an effective treatment of communicating hydrocephalus in children, particularly when it is slowly progressing. It has not yet been evaluated in adults with NPH. Endoscopic third ventriculostomy (ETV) has been shown to be effective in selected cases of NPH. Published results of both endoscopic techniques suggest that complication rates are lower than for CSF shunt surgery. A combination of endoscopic CPC and ETV may provide an attractive alternative to CSF shunting with equivalent rates of responsiveness and lower surgical morbidity. The aim of this study is to evaluate the effectiveness of endoscopic treatment of NPH compared to CSF shunting.

Study Design

An equivalence study, with the null hypothesis that there is no significant difference in outcome between treatment with CSF shunting and treatment with endoscopy 3 months after treatment. Consenting patients with a diagnosis of NPH, satisfying the trial inclusion and exclusion criteria, are randomised to either endoscopic surgery or CSF shunt (control) treatment. The primary outcome measure is the Gait Score [2] at 3 months post-operatively. Secondary outcome measures are: operative mortality, frequency of operative complications, Mattis dementia rating score II, NPH Score, Grooved Pegboard Test score, Quality of life (SF36), modified Rankin score, Barthel index. Outcome assessment is blinded.

Statistical Evaluation

With a sample size of 32 patients in each group, a two group 5% one sided t-test will have 90% power to detect an effect size of 0.75. Sequential monitoring of major morbidity and mortality rates will be undertaken and the trial terminated if these rates exceed a predetermined threshold.

Conclusions

This study aims to evaluate the efficacy and safety of endoscopic CPC with ETV in the treatment of NPH. An interim analysis of results will be presented.

References

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