TROPHY registry

Among children with hydrocephalus, neonates with intraventricular hemorrhage (IVH) and posthemorrhagic hydrocephalus (PH) are considered a group with one of the highest complication rates of treatment. Despite continued progress in neonatal care, a standardized and reliable guideline for surgical management is missing for this challenging condition. Thus, further research is warranted to compare common methods of surgical treatment. The introduction of neuroendoscopic lavage has precipitated the establishment of an international registry aimed at elaborating key elements of a standardized surgical treatment.

The registry is designed as a multicenter, international, prospective data collection for neonates aged 41 weeks gestation, with an indication for surgical treatment for IVH with ventricular dilatation and progressive hydrocephalus. The following initial temporizing surgical interventions, each used as standard treatment at participating centers, will be compared: external ventricular drainage (EVD), ventricular access device (VAD), ventricular subgaleal shunt (VSGS), and neuroendoscopic lavage (NEL). Type of surgery, perioperative data including complications and mortality, subsequent shunt surgeries, ventricular size, and neurological outcome will be recorded at 6, 12, 36, and 60 months.

An online, password-protected website will be used to collect the prospective data in a synchronized manner. As a prospective registry, data collection will be ongoing, with no prespecified endpoint. A prespecified analysis will take place after a total of 100 patients in the NEL group have been entered. Analyses will be performed for safety (6 months), shunt dependency (12, 24 months), and neurological outcome (60 months).

The design and online platform of the TROPHY registry will enable the collection of prospective data on different surgical procedures for investigation of safety, efficacy, and neurodevelopmental outcome of neonates with IVH and hydrocephalus. The long-term goal is to provide valid data on NEL that is prospective, international, and multicenter. With the comparison of different surgical treatment modalities, we hope to develop better therapy guidelines for this complex neurosurgical condition ¹⁾.

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Thomale UW, Cinalli G, Kulkarni AV, Al-Hakim S, Roth J, Schaumann A, Bührer C, Cavalheiro S, Sgouros S, Constantini S, Bock HC. TROPHY registry study design: a prospective, international multicenter study for the surgical treatment of posthemorrhagic hydrocephalus in neonates. Childs Nerv Syst. 2019 Feb 6. doi: 10.1007/s00381-019-04077-4. [Epub ahead of print] PubMed PMID: 30726526.

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