

EARLY CEREBROLYSIN TREATMENT IN TRAUMATIC BRAIN INJURY: A LARGE RETROSPECTIVE MULTI-CENTRIC COHORT STUDY

Bogdan O. Popescu

Department of Neurology, University Hospital, School of Medicine, 'Carol Davila' University of Medicine, Bucharest, Romania

Laboratory of Molecular Medicine, National Institute of Pathology, Bucharest, Romania

In this study were included 7769 adult patients with traumatic brain injury (TBI), admitted in 10 departments of Neurosurgery in Romania, between 2005 -2010. Patients were managed according to the guidelines, part of them (1618 patients) receiving Cerebrolysin (©, Ever Neuro Pharma, Austria) add-on treatment, started in the first 48 hours after TBI. Exclusion criteria were: life-threatening multiple trauma, severe other associated conditions, epilepsy, concomitant stroke, pregnancy or lactation or other concomitant medication with neuroprotective or nootropic effects, except Cerebrolysin. At baseline, all patients were evaluated according to diagnosis guidelines, following a unique protocol in all 10 centers. From the medical records, general data were collected at admission (gender, age, etiology, medical history, concomitant medication, Glasgow Coma Scale score, clinical neurological examination, CT result, whether a surgical intervention was performed) and at days 10 and 30 post-TBI patients were ranked on Glasgow Outcome Scale (GOS) and Modified Rankin Disability Score (RDS). The safety assessments included adverse events, vital signs, laboratory tests and clinical examinations, extracted from the patient medical records. The primary objective of this study was to test the outcome in Cerebrolysin treated patients compared to the control group, at 10 and 30 days post-TBI, and the secondary objective to evaluate the safety of Cerebrolysin for TBI patients. Cerebrolysin treated patients were separated in 2 groups, according to 2 different drug regimens (20 ml or 30 ml/day), and compared to the control group. Statistical comparison was carried out based on the stratification of patients in subgroups, depending on GCS scores at admission (severe, moderate or mild TBI). In mild TBI, patients treated with Cerebrolysin (20 ml or 30 ml/day) had significantly higher GOS and lower RDS scores at 10 days post-TBI, but not at 30 days post-TBI (probably due to a 'ceiling effect'), as compared to control. In moderate and severe TBI, patients treated with Cerebrolysin (20 ml or 30 ml/day) had significantly higher GOS and lower RDS scores both at 10 days and 30 days post-TBI, as compared to control. Moreover, in all TBI patient population, we found a significant correlation between the dose of Cerebrolysin treatment and the prognosis at both 10 and 30 days post-TBI. In conclusion, this large retrospective study shows significant beneficial effects on outcome of early Cerebrolysin treatment in TBI.