European Brain Injury Consortium (EBIC)

http://www.ebic.nl/

El consorcio fue fundado en 1994 y formalmente establecida como una empresa con carácter benéfico el 4 de agosto de 1995.

Desde entonces ha colaborado con empresas farmacéuticas e instituciones de investigación en el desarrollo y gestión de proyectos importantes. Muchos ensayos clínicos llevados a cabo en neurotraumatología en los últimos años se han diseñado en colaboración con / o coordinados por EBIC. EBIC colabora estrechamente con su homólogo estadounidense ABIC (Consorcio Americano Daño Cerebral).

Ha elaborado directrices para el traumatismo craneoencefálico, con el objetivo de armonizar el tratamiento a través de los centros participantes. Además, un estudio prospectivo, produjo importantes resultados y publicaciones.

Ha desarrollado un formulario de encuesta del Centro con el fin de obtener información actualizada sobre las características de los centros.

Estudios

New studies

NeuroVive Pharmaceuticals AB: European multicenter clinical trial on NeuroSTAT©. The active ingredient of NeuroSTAT© is cyclosporine-A which is considered a promising neuroprotective agent with a number of putative mechanisms, including mythocondrial protection.

Ongoing studies

BHR Pharma: “A Randomized, Double Blind, Placebo Controlled Phase 3 Study to Investigate the Efficacy and Safety of Progesterone in Patients with Severe Traumatic Brain Injury”, also known as the SyNAPSe Study (Study of the Neuroprotective Activity of Progesterone in Severe Traumatic Brain Injuries). Rescue ICP: A study on decompressive craniectomy initiated in the UK by Peter Hutchinson (Cambridge). The aim of this trial is to determine the effectiveness of an operation (decompressive craniectomy), compared to medical management alone, to treat brain swelling and improve outcome. Now expanding. EBIC liaison officers: Juan Sahuquillo, Franco Servadei, Andreas Unterberg, David Menon. Brain IT: EBIC is a partner in the Brain IT project coordinated by Ian Piper (Glasgow). EBIC liaison officers: Juan Sahuquillo, Gordon Murray. Recently completed studies

The Impact Study: The IMPACT studies, initiated in 2003, were formally completed in 2011. This international collaborative venture, supported by the US National Institutes of Health (R01-042691) involved methodological, clinical and statistical expertise. The IMPACT studies aim to develop recommendations for improving the design and analysis of trials in TBI. The main accomplishments are: Initiation of standardization of data collection for TBI: Common data Elements Set standards for prognostic analysis Prognostic models for TBI Recommendations for trial design and analysis; these recommendations have the potential to increase statistical power by up to 50% The IMPACT project has resulted in over 55 publications to date. Full details on the results and accomplishments may be found on the IMPACT website: www.tbi-impact.org Pharmos: Dexanabinol Study (n=861) completed in March 2004. This study showed the lowest overall mortality in severe head injury yet reported.

Unfortunately no beneficial effect of Dexanabinol was found. Trial results were reported (Lancet Neurol 2006; 5:38-45). Various additional manuscripts have resulted from the study: Differences in completion of screening logs between Europe and the United States in an emergency phase III trial resulting from HIPAA requirements Slieker FJ, Maas AI, Kompanje EJ, Stocchetti N. Ann Surg. 2005 Feb; 241(2):382-3. Observer variation in the assessment of outcome in traumatic brain injury: experience from a multicenter, international randomized clinical trial Wilson JT, Slieker FJ, Legrand V, Murray G, Stocchetti N, Maas AI. Neurosurgery. 2007 Jul;61(1):123-8; discussion 128-9. Novo Nordisk: A Phase II study on recombinant factor VIIa in brain contusion. Endorsed by EBIC. Completed in April 2006. Traumatic Intracerebral Hemorrhage Study Group., Progression of traumatic intracerebral hemorrhage: a prospective observational study Narayan RK, Maas AI, Servadei F, Skolnick BE, Tillinger MN, Marshall LF J Neurotrauma. 2008 Jun;25(6):629-39. Solvay Pharmaceuticals: A Randomized, Double blind, Placebo-Controlled Phase 2a Study to Investigate the Safety and Pharmacokinetics after Single and Multiple I.V. Doses of SLV334 in Sequential Cohorts of Patients with Moderate and Severe Traumatic Brain Injury. Unfortunately this study was prematurely ended in 2010 following a takeover of Solvay Pharmaceuticals by Abbott Healthcare. Publication of the study results is in preparation.