EVER PHARMA

STROKE

TBI

DEMENTIA

The effective treatment after TBI

CAPTAIN – Safety and Efficacy of Cerebrolysin® in Neurorecovery after moderate-severe Traumatic Brain Injury

Muresanu, Dafin F., et al. „Efficacy and safety of cerebrolysin in neurorecovery after moderate-severe traumatic brain injury: results from the CAPTAIN II trial." Neurological Sciences (2020): 1-11

The effective treatment after TBI

- Early treatment effects
- Significantly reduced depression
- Improvement of memory and concentration

Cerebrolysin®

Reconnecting Neurons.
Empowering for Life.

The only positive RCT in TBI recovery

Faster reintegration into work- and social-life after TBI with Cerebrolysin®

- Strong effects on **depression**
- Improvement of **cognitive functions**
- Reduction of most **challenging complications** after TBI

Day 90 (PP)	MW Statistic	MW	95,00% -CI	N1/N2	P
Glasgow Outcome Scale Extended		0,5733	(0,4816 to 0,6651)	74/55	0,1172
Early Rehabilitation Barthel Index		0,5252	(0,4810 to 0,5693)	74/55	0,2634
Mini - Mental State Examination		0,5692	(0,4777 to 0,6606)	74/55	0,1381
Processing Speed Index - Digit Symbol Coding		0,6430	(0,5394 to 0,7466)	74/55	0,0068
Processing Speed Index - Symbol Search		0,5609	(0,4597 to 0,6621)	74/55	0,238
Stroop (VST) Word/ Dots Interference		0,6661	(0,5682 to 0,7640)	74/55	0,0009
Stroop (VST) Color - Word/ Dots Interference		0,5916	(0,4934 to 0,6899)	74/55	0,0675
Digit Span Digit Forward Test		0,6264	(0,5231 to 0,7296)	71/55	0,0164
Digit Span Digit Backward Test		0,6694	(0,5654 to 0,7733)	71/55	0,0014
Color Trails Test 1		0,6342	(0,5350 to 0,7333)	71/55	0,008
Color Trails Test 2		0,5965	(0,4969 to 0,6962)	71/55	0,0575
HADS - Anxiety Sumscore		0,5318	(0,4309 to 0,6326)	71/55	0,5371
HADS - Depression Sumscore		0,6458	(0,5465 to 0,7452)	71/55	0,004
(Combined) Wei - Lachin		**0,6026**	**(0,5297 to 0,6755)**	**74/55**	**0,0058**

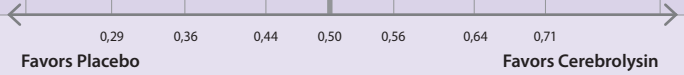

Figure: Multidimensional Ensemble, Day 90, PP

- Improvement of global outcome with Cerebrolysin®
- Effect size of Cerebrolysin® has medium superiority
- **Statistically significant** on day 90
- All 13 single outcome scales show superiority of Cerebrolysin® as compared to placebo
- Stand-alone **statistical significance for 6 outcome scales**

Title: Efficacy and safety of Cerebrolysin® in Neurorecovery after moderate-severe traumatic brain injury: Results from the CAPTAIN II trial

Patients: 80 Cerebrolysin® group + 59 Placebo group = 139 patients in total

Treatment: Treatment Cycle 1 = Day 1 – 10 : 50 ml/day
Treatment Cycle 2 = Day 31 – 40 : 10 ml/day
Treatment Cycle 3 = Day 61 – 70 : 10 ml/day

ABBREVIATED PRESCRIBING INFORMATION - Cerebrolysin. Name of the medicinal product: Cerebrolysin - Solution for injection. Qualitative and quantitative composition: One ml contains 215.2 mg of Cerebrolysin concentrate in aqueous solution. List of excipients: Sodium hydroxide and water for injection. Therapeutic indications: For treatment of cerebrovascular disorders. Especially in the following indications: Senile dementia of Alzheimer's type. Vascular dementia. Stroke. Craniocerebral trauma (commotio and contusio). Contraindications: Hypersensitivity to one of the components of the drug, epilepsy, severe renal impairment. Marketing Authorisation Holder: EVER Neuro Pharma GmbH, A-4866 Unterach. Only available on prescription and in pharmacies. More information about pharmaceutical form, posology and method of administration, special warnings and precautions for use, interaction with other medicinal products and other forms of interaction, fertility, pregnancy and lactation, effects on ability to drive and use machines, undesirable effects, overdose, pharmacodynamics properties, pharmacokinetic properties, preclinical safety data, incompatibilities, shelf life, special precautions for storage, nature and contents of the container and special precautions for disposal is available in the summary of product characteristics. (Reference SPC – CCDS Version 2.0/03.06.2016)

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