

A BROAD ANALYSIS OF SAFETY DATA with A VERY PRECISE STATISTICAL RELEVANCE & EXPLANATORY POWER SHOWS THAT A **CEREBROLYSIN®** TREATMENT in **Stroke** Patients:

 **IMPROVES CLINICAL SAFETY**

 **HAS A CLEAR CLINICAL TREATMENT BENEFIT**

 **LOWERS THE MORTALITY**

Cerebrolysin® dosage for stroke patients

Daily dosage	Initiation of treatment	Treatment Duration
20 - 50ml	as soon as possible	10 - 21 days



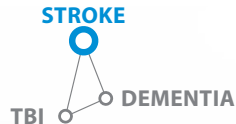
Title: Safety of Cerebrolysin for Neurorecovery after Acute Ischemic Stroke: A Systematic Review and Meta-Analysis of Twelve Randomized-Controlled Trials
Author: S. Strilciuc, et al.
Journal: Pharmaceuticals
URL: <https://pubmed.ncbi.nlm.nih.gov/34959697/>

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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 Authorization 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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www.everpharma.com
www.cerebrolysin.com



Cerebrolysin®
improves treatment safety

Confirmed by multiple trials



**Quality from
Austria.**

Cerebrolysin®
Reconnecting Neurons.
Empowering for Life.

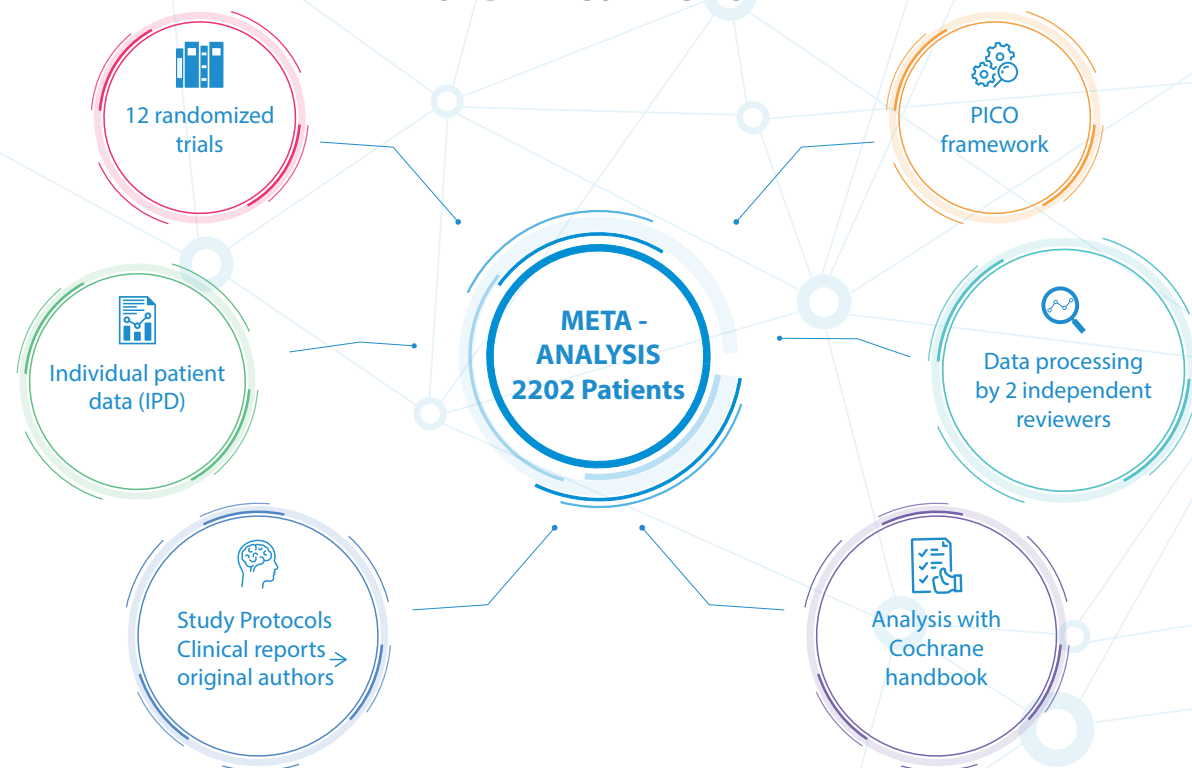
CERE/INT/01/2023/1



CLEAR IMPULSE TO IMPROVE THE CLINICAL SAFETY

Safety of **Cerebrolysin®** for Neurorecovery
A new Systematic Review by Strilciuc et al., 2021

MOST COMPREHENSIVE SAFETY META-ANALYSIS PERFORMED FOR **CEREBROLYSIN®** - A BROAD APPROACH OF DATA COLLECTION



NEW BROAD ANALYSIS OF SAFETY DATA FOR **CEREBROLYSIN®**

12 randomized placebo controlled trials

2202 patients

Inclusion of the **largest number of studies** on **Cerebrolysin®** after stroke

Maximum of safety-related data

Following-up with **primary source references**

Requesting **additional material** from **original authors**



COCHRANE METHODOLOGY USED

Data collection and analysis **according to the Cochrane Handbook for Systematic Reviews of Interventions**



VERY PRECISE STATISTICAL RELEVANCE AND EXPLANATORY POWER

Accurate selection criterias and statisticals methods

PICO framework used

Robustness of the safety results

All-cause Deaths - Comparison of **Cerebrolysin®** versus Placebo

Study or Subgroup	Cerebrolysin®		Placebo		Weight	Risk Ratio	Risk Ratio
	Events	Total	Events	Total		M-H, Random, 95% CI	M-H, Random, 95% CI
Ladurner 2005	6	78	6	68	12.8%	0.87 [0.29, 2.58]	
Skvortsova 2004	2	20	3	20	5.3%	0.67 [0.12, 3.57]	
Shamalov 2010	1	24	2	23	2.8%	0.48 [0.05, 4.93]	
Gharagozli 2017	1	50	2	50	2.7%	0.50 [0.05, 5.34]	
Heiss 2012	28	529	32	540	61.9%	0.89 [0.55, 1.46]	
Lang 2013	4	60	4	59	8.4%	0.98 [0.26, 3.75]	
Amiri-Nikpour 2014	1	23	2	23	2.8%	0.50 [0.05, 5.14]	
Muresanu 2016	0	104	4	104	1.8%	0.11 [0.01, 2.04]	
Guekht 2015	2	120	0	120	1.6%	5.00 [0.24, 103.06]	
Chang 2016	0	35	0	35		Not estimable	
Xue 2016	0	28	0	29		Not estimable	
Stan 2017	0	30	0	30		Not estimable	
Total (95% CI)		1101		1101	100.0%	0.83 [0.57, 1.23]	
Total events	45		55				

Heterogeneity: Tau² = 0.00; Chi² = 3.99, df = 8 (p = 0.86); I² = 0%

Test for overall effect: Z = 0.92 (p = 0.36)

Safety Population, Random Effects, M-H, Risk Ratio (RR)

Cerebrolysin® shows a tendency for overall reduction in all-cause deaths



CEREBROLYSIN® LOWERS MORTALITY

Cerebrolysin® shows a tendency for **overall reduction** in **all-cause deaths**

Deaths evaluated by means of risk ratio (RR)



50ML **CEREBROLYSIN®** IMPROVES TREATMENT SAFETY

Lowest SAE and non-fatal SAE rates

25% risk reduction regarding SAEs

Very good safety profile for **Cerebrolysin®** treated patients

Safety parameters defined in compliance with EMA definitions

No safety issues