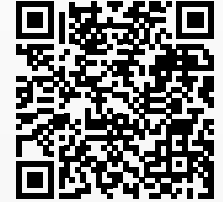




DEMENTIA

STROKE

TBI



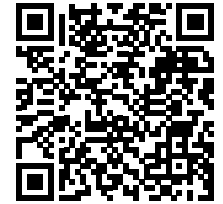
Webinar EVER Pharma Evidence-based neurorecovery after stroke and TBI

April 6, 2022

Cerebrolysin®

Reconnecting Neurons.
Empowering for Life.

Evidence-based neurorecovery after stroke and TBI



SPEAKERS



Johannes Leitgeb

Medical University of Vienna, Austria.
Trauma surgeon.

Moderator



Christian Matula

Professor and Vice-Chairman Department of Neurosurgery, Medical University of Vienna, Austria

Topic: Evidence-based neurorecovery after stroke and TBI

INTRODUCTION

On April 6th Professor Christian Matula – Professor and Vice-Chairman Department of Neurosurgery, Medical University of Vienna, Austria – spoke to an international community of medical professionals about the global burden of brain trauma, expertly moderated by Professor Johannes Leitgeb - Trauma surgeon, Medical University of Vienna, Austria.

In this review we will highlight the main messages of Dr. Matula's talk.

The global burden of Neurotrauma

Pathophysiology of brain trauma

History of negative clinical research and a rationale for failure

A breakthrough in brain trauma research – The CAPTAIN-Trial Methodology and trial series

Cerebrolysin in hemorrhagic stroke – promising evidence and safety data

A call to action – neurotrauma patients need multidisciplinary teams to improve outcome

The global burden of Neurotrauma

Globally over 70 Million patients suffer from brain injury each year and this incurs enormous socioeconomic costs as mainly male man at working age are affected, often not able to continue providing income for their families. In addition the highest incidences are found in low-and middle income countries where the treatment infrastructure and also the reintegration possibilities for these patients are limited.

Pathophysiology of brain trauma

Brain Trauma, particularly the more severe forms, constitute a very complex field in medicine. Multiple processes start after brain injury and for many life-threatening symptoms essential treatments exist, either surgical procedures to treat e.g tissue compression or bleeding or pharmacological agents indicated for infections or swelling. Of particular investigative interest have been neuroprotective and neurorestorative agents like Cerebrolysin, limiting cell death and accelerating recovery.

History of negative clinical research and a rationale for failure

In relation to the global burden of neurotrauma not many pharmacological agents have been researched in a serious way, aiming to provide strong evidence based on clinical trials conducted state of the art. The exception are agents like Citicoline, Erythropoietin, Progesterone, or innovative treatment methods like hypothermia. Unfortunately, all these trials failed and exemplify the difficulty to conduct this research.

What are the reasons for such long lasting failures despite valiant efforts?

The reasons are manifold and complex – see the list of reasons in the table and only if the majority of these factors are taken into consideration successful trials can be expected.

A breakthrough in brain trauma research – The CAPTAIN-Trial Methodology and trial series

Dr. Matula shared his own involvement into the research with Cerebrolysin as member of the Steering Committee of the CAPTAIN-Methodology and trial series, highlighting why Cerebrolysin constitutes to be an excellent candidate to provide evidence in brain recovery after trauma.

He spoke convincingly about the multimodal properties of Cerebrolysin acting at different time-points and at different levels of the ischemic cascade therefore activating or strengthening specific biological responses for the injured brain.

Additionally, the CAPTAIN design and study methodology avoided most potential pitfalls mentioned as negatively contributing factors.

The CAPTAIN trial also used a progressive biometric approach, avoiding dichotomization resulting in measuring all improvements in all assessments, the so-called multidimensional methodology.

It became obvious in Prof Matula's presentation that the positive results of the CAPTAIN trial series constitute a true breakthrough in a field of medicine with many unmet needs and confidence was expressed that further trials will strengthen this evidence even more...

...while also expressing confidence that these studies will have an impact on international and local guidelines.

He also highlighted two more very important findings from the CAPTAIN trials – the impressive results in one of the most prominent post-TBI complications – depression and the safety aspects.

As shown below, depression occurs in over 60 % of TBI patients in their lifetime and Cerebrolysin showed particularly strong results in this domain.

He also demonstrated that Cerebrolysin is not only a safe but a safety-enhancing agent as proven in the safety analysis of the CAPTAIN Meta Analysis.

Cerebrolysin in hemorrhagic stroke – promising evidence and safety data

When briefly discussing the latest evidence in the Cerebrolysin research, Prof. Matula pointed out that these data deserve a lot of attention. He mentioned that hemorrhagic stroke is a field, similar to brain trauma, with a lot of unmet patient needs but very few compounds are involved in active clinical research to show improvements in recovery.

The pilot study results with Cerebrolysin from the CESAR-study and the retrospective data sets from Korea (SAHRR) have to be seen and appreciated in this context. In both trials Cerebrolysin shows promising efficacy data as well as enhancing the safety of patients whose risk of mortality is the highest in all stroke etiologies.

A call to action – neurotrauma patients need multidisciplinary teams to improve outcome

In his final part of the lecture Dr. Matula passionately asked all medical professional groups treating neurotrauma patients to form multidisciplinary teams in order to ensure a much-needed paradigm shift in treatment – from short-term focus to long-term follow-up in order to detect and treat the late onset of complications like cognition, memory, depression and other neurocognitive disorders.

He introduced a new educational program starting in Vienna between May 16th and 20th – the Neurotrauma Simulation Centre Vienna (NTSC Vienna) which will bring together different teams from specific countries organized into multidisciplinary teams who are involved in the chain of recovery of neurotrauma patients.

This project has been developed by a group of trauma experts from Vienna, incl. the speaker and the moderator of this webinar, and is part of the efforts of the Academy of Multidisciplinary Neurotraumatology (AMN), a medical society whose goal it is to improve neurotrauma care by implementing the ideas of multidisciplinary care.

This project is facilitated by EVER Neuro Pharma and also our company aims to contribute strongly to improving treatment standards and processes in this field.



ABBREVIATED PRESCRIBING INFORMATION. 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.

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EVER Neuro Pharma GmbH
Oberburgau 3
4866 Unterach
Austria
www.everpharma.com

www.cerebrolysin.com