Cerebrolysin is a multi-modal neuropeptide drug which improves the brain's ability for self-repair by stimulating neurorecovery.

**Cerebrolysin**
neurontic factors like activities

- Neuron death via distinct caspases, Nature 2009;Feb19;457(7232):981-9
- Oxidative stress
- Inflammation
- NEUROPROTECTION (Protection, effect)
- NEURORECOVERY (Activation, effect)
- NEUROTROFICITY (Promote growth of new neurons)
- Synaptogenesis (Development of new synapses)
- Neuroplasticity (Repair and remodeling)
- Neurogenesis (Production of new neurons)
- Sprouting (Increase in number of neuromatrical branches)
- Kinases (PI3K-Akt)
- NEUROPLASTICITY Synaptogenesis
- NEUROTROFICITY Pleiotropic effect
- NEURORECOVERY Kynurenine, tryptophan, and serotonin pathways.
- NEUROPROTECTION Anti-oxidative mechanisms, cell cycle, and inflammation.
- Neuroplasticity Repair and remodeling.
- Neurogenesis Production of new neurons.
- Sprouting Increase in number of neuromatrical branches.
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The global benefit is a composite of the global clinical change and the cognitive function:

- **ZVT**

For the efficacy criteria of individual studies:

- **CBIC** Clinical Interview-Based Impression of Change plus caregiver report
- **CGI** Clinician's Global Impression of Change (Item 2 of CGI)
- **ADAS-cog+ Alzheimer's Disease Assessment Scale – cognitive subpart – modified (14 items)**
- **MMSE Mini-Mental State Examination**
- **ZVT Trail-Making Test**

**Global clinical change** after 4 weeks treatment with Cerebrolysin was 3 times higher as compared to placebo. The effect was statistically significant.

At 6 months follow-up the chance for global clinical improvement was 5 times higher as compared to placebo. The effect was statistically significant.

The safety aspects of Cerebrolysin were comparable to placebo.

There is a positive benefit-risk ratio in favor of Cerebrolysin with the NNT for benefit of 2.9 with respect to the 6-months global clinical change and the calculated NNT for harm of 501 with respect to risk (patients with premature discontinuation due to AEs). The FDA (FDA and Drug Administration) considers cognitive and global endpoints as the most important domains when assessing anti-dementia treatments.

**Summary**

- Statistically significant advantage of Cerebrolysin over placebo was observed in all 3 criteria
- 3 times higher (after 4 weeks) and 5 times higher (after 6 months) improvements of GIC (Global Clinical Change) were shown compared to placebo
- The safety aspects of Cerebrolysin were comparable to placebo, thus suggesting a favorable benefit-risk ratio in patients with mild-to-moderate Alzheimer's disease
- Results are comparable to oral standard therapy but provide better safety results

**Positively Significant Treatment Effects**

**Cognitive function**
- Beneficial and statistically significant treatment effects of Cerebrolysin after 1 month
- Significant beneficial treatment effects of Cerebrolysin after 6 months
- Beneficial and statistically significant treatment effects of Cerebrolysin compared to placebo.

**Global benefit**: The statistically significant advantage of Cerebrolysin over placebo was maintained for at least 6 months.