
# Discover the Power of Neuro Regenerative Peptides


- Edwin Lee, MD., FACE
- Institute for Hormonal Balance, Orlando
- Co Founder of Clinical Peptide Society

- Feb 2024


# Nothing to Disclose

# 83 year old with Alzheimer's 2015

# In end of Dec of 2017

## she came to see me in my office

- She was on anti depressants, anti anxiety medications and memantine (Namenda)
- Her blood work showed low on all of hormones
- She received a week of IV nutrition
- She got on Vitamin D, estradiol patch, progesterone and a peptide called Cerbrolysin 215 mg IM 5 times a week.

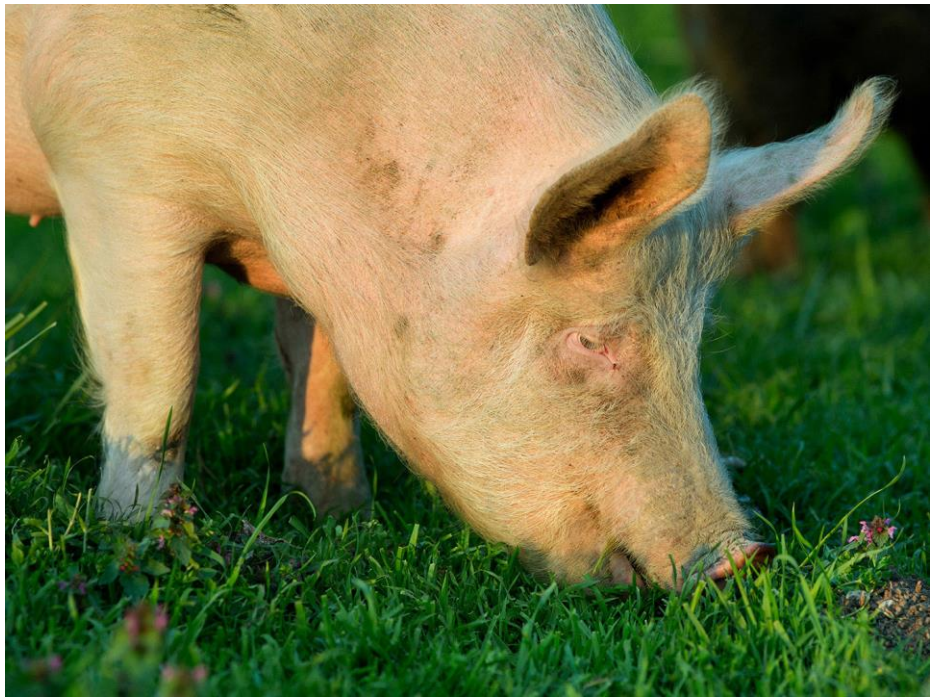
# 2019 a little over 1 year later- 87 years old

# Nootropic agent

- Substance that enhances cognition and memory and facilitates learning
- Cerebrolysin
- Semax
- Selank
- TB4

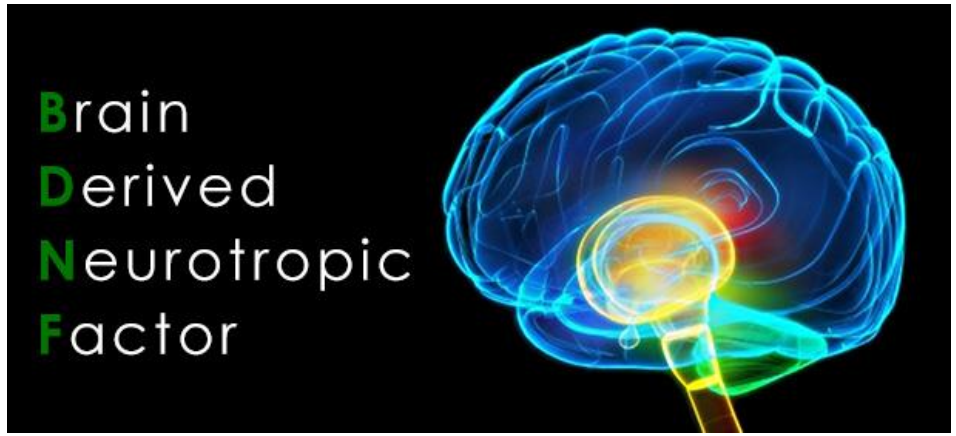
# Cerebrolysin (Biologic with many peptides)

- Discovered by an Austrian professor Gerhart Harrer in 1949
- Mixture of many neuropeptides and amino acids
- Enzymatic hydrolysis of the young pig brain tissue produces substances that can stimulate nerve cells.



# Cerebrolysin

- Registered in Austria as a drug in 1954
- First publications of clinical trials dated 1954-55



# Cerebrolysin

Berk, C., & Sabbagh, M. N. (2013). Successes and failures for drugs in late-stage development for Alzheimer's disease. *Drugs & aging*, *30*(10), 783–792. doi:10.1007/s40266-013-0108-6

- Cerebrolysin is currently approved for use in over 50 countries as a treatment for dementia and stroke
- Approved for use in Austria, China, Germany, Russia and South Korea
- Not FDA approved in the US

Cerebrolysin®

# Cerebrolysin contains

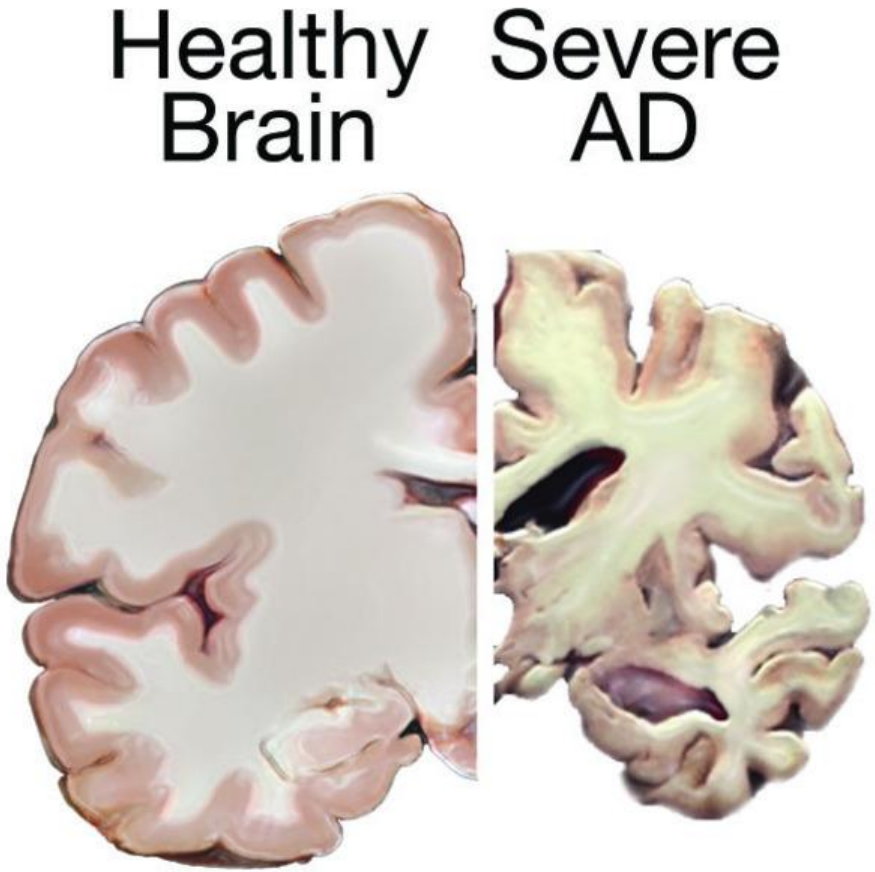
- Glial cell line derived neurotrophic factor (GDNF)
- Nerve growth factor (NGF)
- Ciliary neurotrophic factor (CNTF)

- Menon PK, et al. CNS Neurol Disord Drug Targets. 2012 Feb;11(1):40-9.

# Cerebrolysin

- Meta-Analysis of 6 randomized double-blind placebo-controlled studies on 30 ml/day of Cerebrolysin in mild-to-moderate AD
- All Studies had 20 IV infusion of 30 ml of Cerebrolysin during the first month


- Gauthier S, et al (2015) Cerebrolysin in mild-to-moderate alzheimer's disease: a meta-analysis of randomized controlled clinical trials. Dement Geriatr Cogn Disord 39:332–347.

# Results of 6 studies using Cerebrolysin

Gauthier S, et al (2015) Cerebrolysin in mild-to-moderate alzheimer's disease: a meta-analysis of randomized controlled clinical trials. Dement Geriatr Cogn Disord 39:332–347.

- Mean of age varied from 70 to 74 y.o.
- Cerebrolysin was significantly more effective than placebo at 4 weeks and 6 months regarding cognitive function

# Cerebrolysin with Aricept

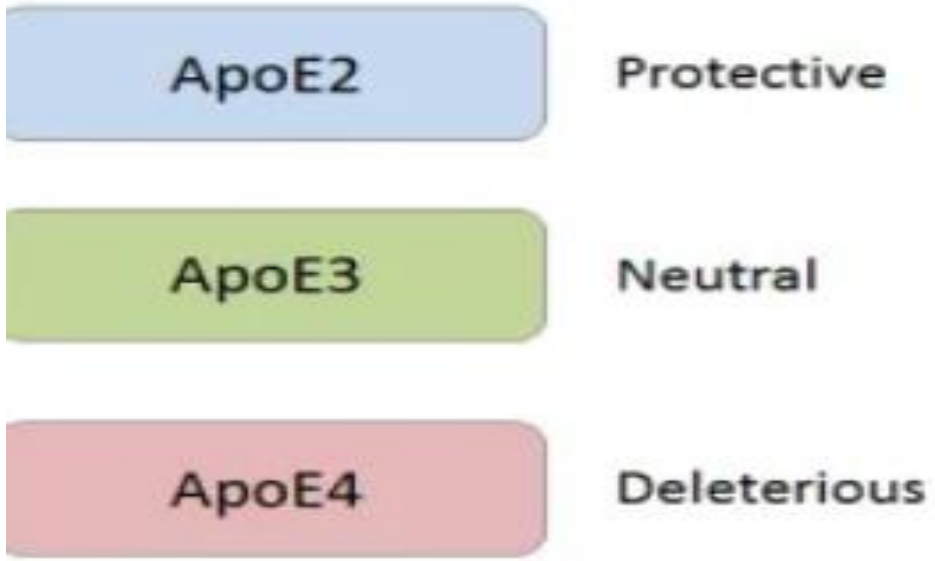
Alvarez X, et al *International Journal of Neuropsychopharmacology*, (2016) 19(6): 1–6

- Low BDNF has been associated with Alzheimer's disease
- Recent 2016 Randomized double blind trial showed Cerebrolysin increases BDNF
- Combination of Cerebrolysin with donepezil (acetylcholinesterase inhibitor) increases BDNF

# Cerebrolysin with Apo E4

Alvarez X, et al *International Journal of Neuropsychopharmacology*, (2016) 19(6): 1–6

- BDNF increases were greater in apolipoprotein E4 allele carriers
- Higher BDNF levels were associated with better cognitive improvements



# Cerebrolysin in first degree relatives with Alzheimer's

- 67 relatives with minimal cognitive dysfunction (mean age 57.6)
- IV Cerbrolysin 20 ml/d
- Treatment was 1 month
- Improvement in cognition


- Selezneva ND, et al. Zh Nevrol Psikhiatr Im S S Korsakova. 2018;118(10):30-36.



Review > Drugs Today (Barc). 2012 Apr:48 Suppl A:25-41.

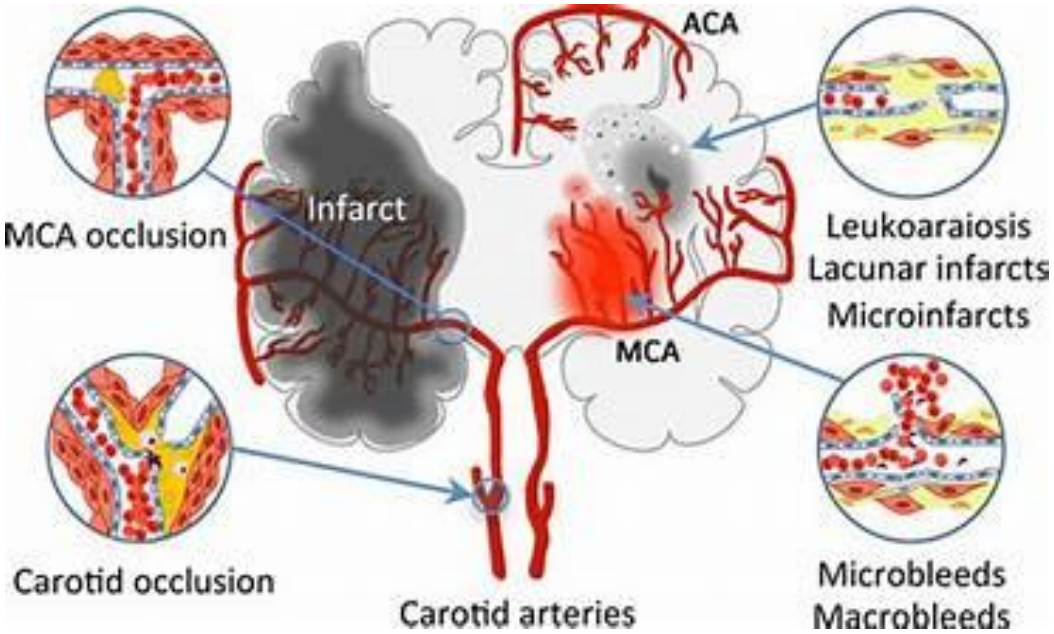
doi: 10.1358/dot.2012.48(Suppl.A).1739721.

# Cerebrolysin improves symptoms and delays progression in patients with Alzheimer's disease and vascular dementia

R F Allegri [1], A Guekht

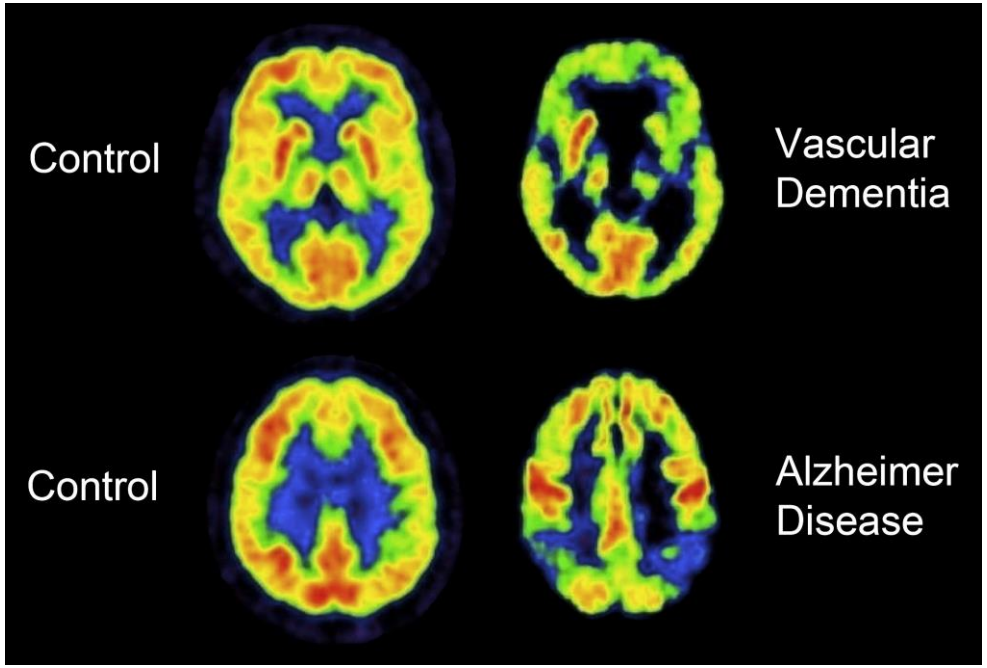
Guekht AB, et al. Cerebrolysin Investigators. Cerebrolysin in vascular dementia: improvement of clinical outcome in a randomized, double-blind, placebo-controlled multicenter trial. J Stroke Cerebrovasc Dis. 2011 Jul-Aug;20(4):310-8

- Multicenter, double-blind, placebo-controlled study in 242 patients with vascular dementia
- 24 weeks of treatment
- Intravenous Cerebrolysin 20 mL was administered once daily over the course of 2 treatment cycles



Guekht AB, et al. Cerebrolysin Investigators. Cerebrolysin in vascular dementia: improvement of clinical outcome in a randomized, double-blind, placebo-controlled multicenter trial. J Stroke Cerebrovasc Dis. 2011 Jul-Aug;20(4):310-8

- Cerebrolysin significantly improved clinical outcome in vascular dementia
- Cerebrolysin was safe and well tolerated.



# Used in over 50 countries

Review > Neurol Sci. 2021 Apr;42(4):1345-1353. doi: 10.1007/s10072-021-05089-2.
Epub 2021 Jan 30.

## Cerebrolysin for stroke, neurodegeneration, and traumatic brain injury: review of the literature and outcomes

Brian Fiani [1], Claudia Covarrubias [2], Amelia Wong [3], Thao Doan [4], Taylor Reardon [5], Daniel Nikolaidis [6], Erika Sarno [7]

# Cerebrolysin dosing

Stan A, et al., **Cerebrolysin and early neurorehabilitation in patients with acute ischemic stroke: a prospective, randomized, placebo-controlled clinical study** *Journal of Medicine and Life Vol. 10, Issue 4, October-December 2017,* **pp.216-222**

- Dosing used in studies were 10- 30 ml/ day IV 5 days a week.
- Concentration is 215.2 mg/ml
- Comes in 10 ml ampules

- Optional dosing
- Infuse 30 ml (6456 mg) in 250 cc of normal saline over 1 hour 2-3 times a week. Recommend using a filter
- 1 ml (215.2 mg) IM shot 3-5 times a week

# Global Provider Alliance

- GPA does not profit on any prescribed products
- GlobalProviderAlliance.org
  - Contact is Liz at Liz@globalproivderalliance.org
- Zadaxin (TA1) 10 mg vial $75
- Cerebrolysin 1 box of 5 x 10 ml ampules $135 ( 1 month )
- 3 months of Cerebrolysin = 3 boxes = $405
- International Physician Consultation is $55
- Shipping fee is $60 – takes 2- 3 weeks from Thailand

# Experimental Dosing for optimal brain function

- Cerebrolysin comes in a 10 ml ampule, inject 1 ml IM once a week to 2-3 times a week.
- The rest of the 9 ml draw up with a needle and syringe with use a filter.  Store in a sterile vial (amber vial) for multiuse

# If your parent has early dementia then what would you do to help your mom or dad?

# What about infants with a brain injury?

J Clin Neurol. 2016 Jan; 12(1): 79–84.
Published online 2015 Sep 11. doi: 10.3988/jcn.2016.12.1.79
PMCID: PMC4712290
PMID: 26365023

## Safety and Efficacy of Cerebrolysin in Infants with Communication Defects due to Severe Perinatal Brain Insult: A Randomized Controlled Clinical Trial

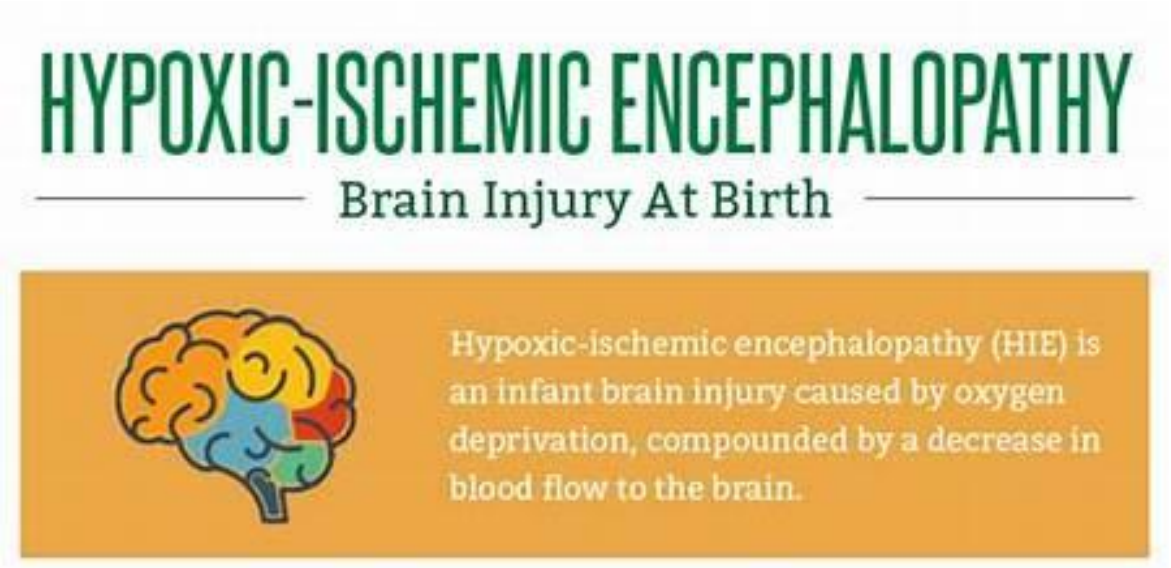
Sahar M.A. Hassanein,[a] Shaymaa M. Deifalla,[a] Moustafa El-Houssinie,[b] and Somaia A. Mokbel[c]



Journal Article

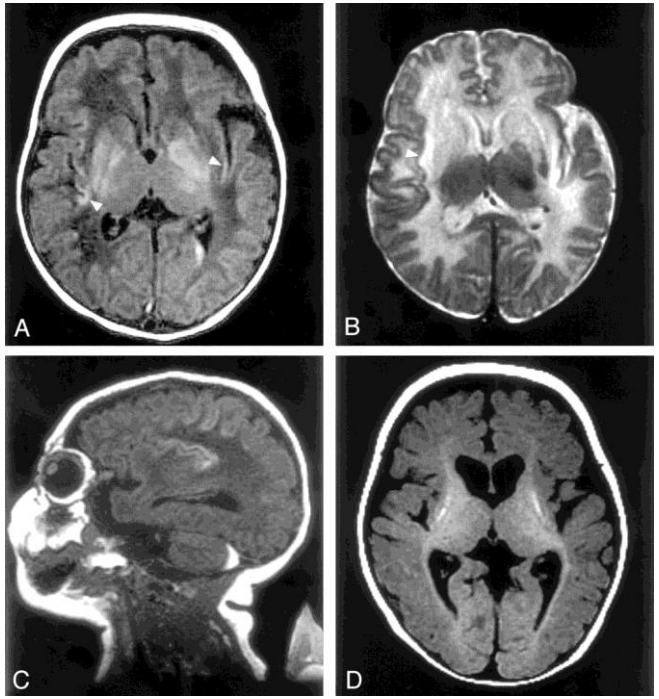
Hassanein SM, et al. Safety and Efficacy of Cerebrolysin in Infants with Communication Defects due to Severe Perinatal Brain Insult: A Randomized Controlled Clinical Trial. J Clin Neurol. 2016 Jan;12(1):79-84. doi: 10.3988/jcn.2016.12.1.79. Epub 2015 Sep 11

- Randomized placebo-controlled clinical trial was conducted in which 158 infants (age 6-21 months)
- No cure or treatment for brain insult in infants and children.
- Cerebrolysin injections 2 x week of 0.1 mL/kg body weight for 5 weeks (total of ten injections)



Hassanein SM, et al. Safety and Efficacy of Cerebrolysin in Infants with Communication Defects due to Severe Perinatal Brain Insult: A Randomized Controlled Clinical Trial. J Clin Neurol. 2016 Jan;12(1):79-84. doi: 10.3988/jcn.2016.12.1.79. Epub 2015 Sep 11

- Early intervention after perinatal brain insult may enhance brain plasticity and the recovery of impaired function.
- Cerebrolysin induces stem-cell (neural progenitor cells) proliferation in the brain contributing to neruogenesis



Hassanein SM, et al. Safety and Efficacy of Cerebrolysin in Infants with Communication Defects due to Severe Perinatal Brain Insult: A Randomized Controlled Clinical Trial. J Clin Neurol. 2016 Jan;12(1):79-84. doi: 10.3988/jcn.2016.12.1.79. Epub 2015 Sep 11

- Cerebrolysin dramatically improved infants' communication especially symbolic behavior which positively affected social interaction.

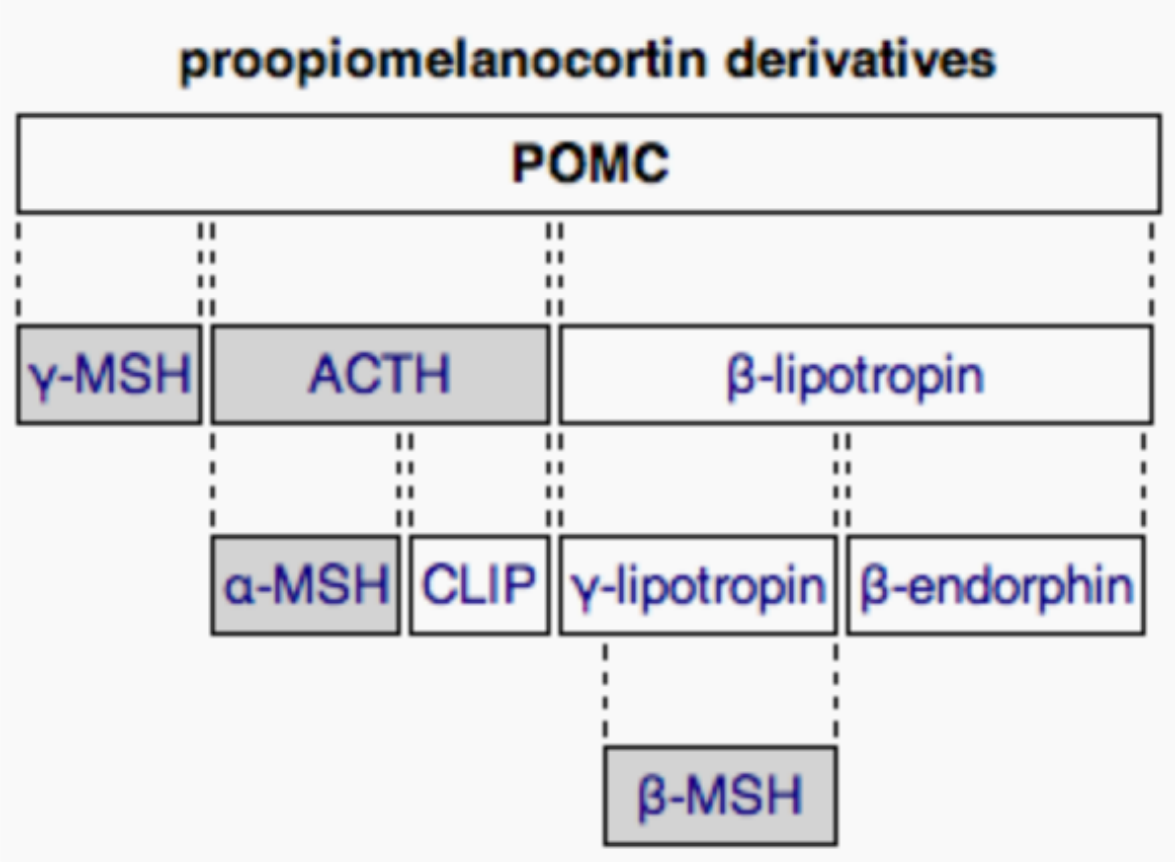
- Cerebrolysin increased from baseline
- 65.44% (social), 45.54% (speech), 358.06% (symbolic), 96.00% total scores. ($p<0.001$)

# What dose would you recommend for an adult with dementia?

# Nootropic agent

- Substance that enhances cognition and memory and facilitates learning
- Cerebrolysin
- Semax
- Selank
- TB4

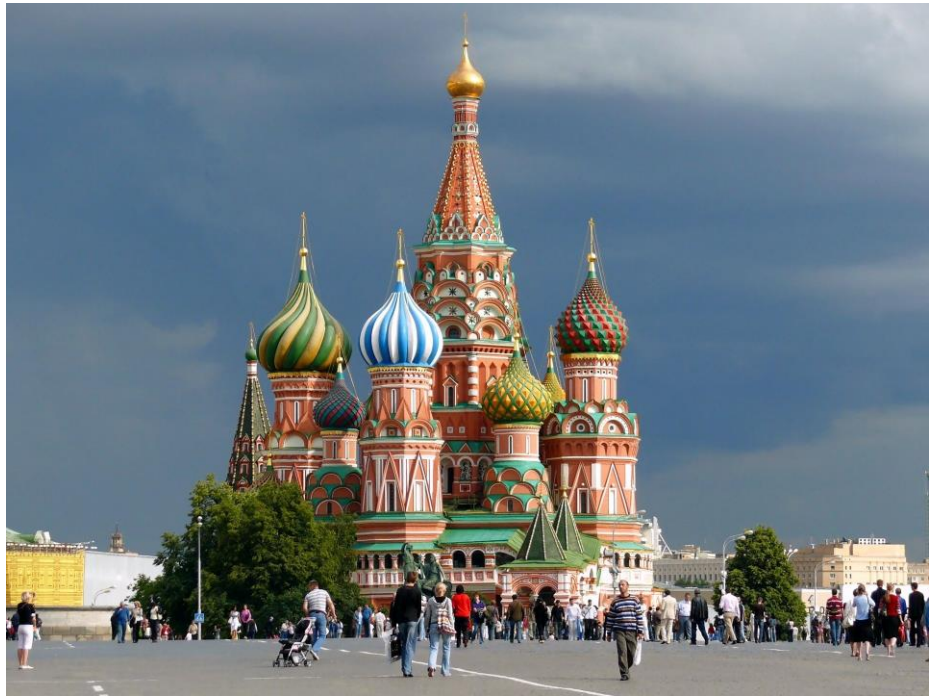
# Semax (7 amino acid analog to ACTH 4-10)



# Semax (analogue of ACTH (4-10))

- Discovered and research in Russia (unfortunately a lot of studies are all in Russian without an abstract)
- 7 Amino acid
- Has no hormonal activity


- Tsai SJ. Med Hypotheses. 2007;68(5):1144-6. Epub 2006 Sep 25.

# Semax (analogue of ACTH (4-10))

- Study in rat brains occluding the middle cerebral artery
- Shown to increase brain-derived neurotrophic factor (BDNF), NGF (Nerve growth factor) TrkB (tyrosine kinase receptor type 2)

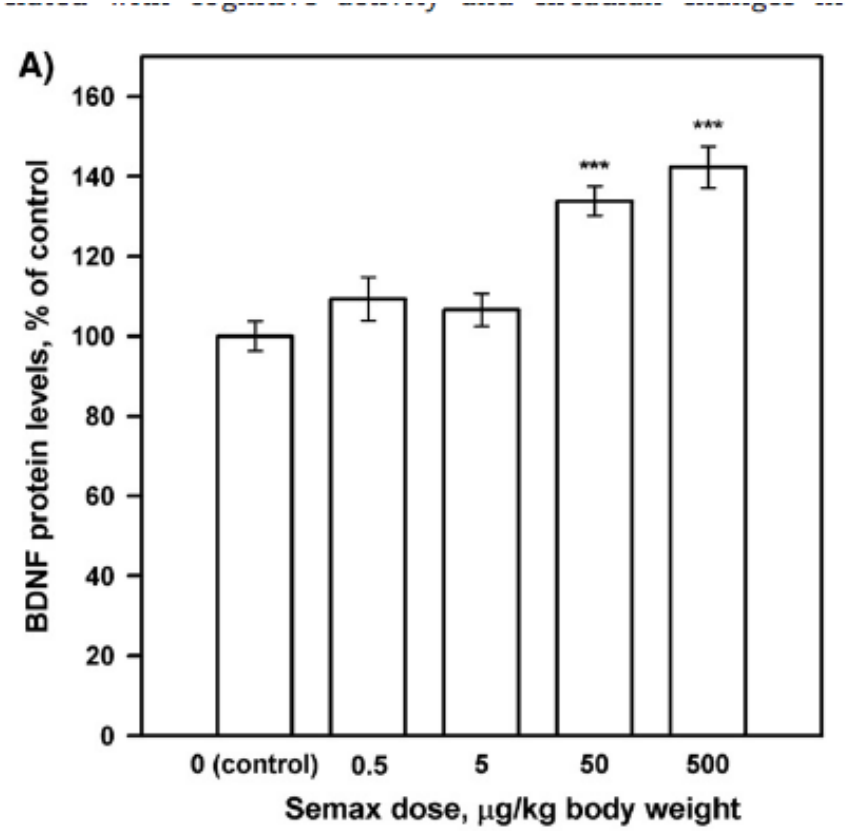
- Tyrosine kinase receptor type 2 (TrkB), which has the highest affinity for brain-derived neurotrophic factor (BDNF) and is involved in neuronal plasticity

- Dmitrieva VG, et al. Cell Mol Neurobiol. 2010 Jan;30(1):71-9

# Semax intranasal increases BDNF & TrkB)

- Study in rats given a single application of Semax (50µg/kg body weight) results in a increase of BDNF and TrkB

- Dolotov OV, et al. Semax, an analog of ACTH(4–10) with cognitive effects,regulates BDNF and trkB expression in the rat hippocampus. BRAIN RESEARCH 1117 (2006) 54–60



# Semax is a nootropic peptide

- 1997 a paper published 15 years experience
- Semax significantly improves memory and attention in healthy men under extreme conditions of activities



- Asmarin IP, et al. Zh Vyssh Nerv Deiat Im I P Pavlova. 1997 Mar-Apr;47(2):420-30.

# Semax in stroke

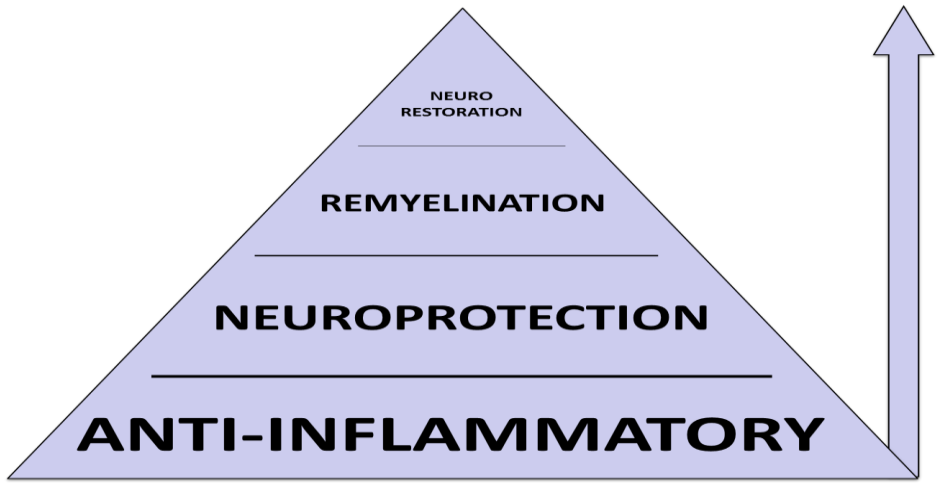
Gusev El, et al. Zh Nevrol Psikhiatr Im S S Korsakova. 1997;97(6):26-34

- Study of 30 patients with acute ischemic stroke
- Semax improved in the recovery of stroke clinically and by EEG
- 12 mg for moderate stroke
- 18 mg for severe stroke
- Tx course--5 and 10 days

# Semax is neuroprotective

- Study on neurons with glutamate toxicity
- Semax improved neuronal survival by on average 30%

- Storozhevykh TP, et al. Bull Exp Biol Med. 2007 May;143(5):601-4.



# Dosing of Semax

- Semax has a poor oral deliverly
- Can be delivered by Subcutaneous or intranasal

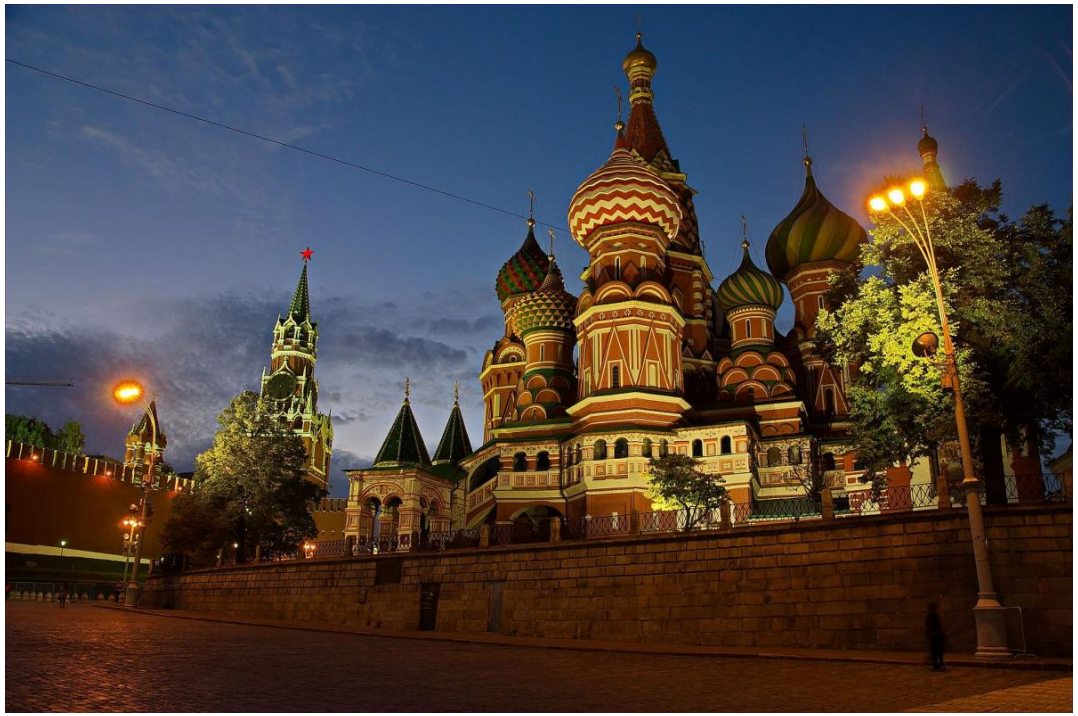
- Suggested dosing
- 750 mcg per nasal spray in each nostril once a day.  (total dose of 1500 mcg)

# Nootropic agent

- Substance that enhances cognition and memory and facilitates learning
- Cerebrolysin
- Semax
- Selank
- TB4

# Selank

- Discovered and research in Russia (unfortunately a lot of studies are all in Russian without an abstract)
- 7 Amino acid
- It is a synthetic analogue of human tuftsin. (part of the Fc domain of IgG)



# Selank

**Zozulia AA, et al. Efficacy and possible mechanisms of action of a new peptide anxiolytic selank in the therapy of generalized anxiety disorders and neurasthenia.** Zh Nevrol Psikhiatr Im S S Korsakova. 2008;108(4):38-48.

- Main effect is that it helps with anxiety
- Study of 62 patients with Generalized Anxiety Disorder, Selank reduced anxiety without having any sedative properties

# Selank

Inozemtseva LS, et al. **Intranasal administration of the peptide selank regulates BDNF expression in the rat hippocampus in vivo.** Dokl Biol Sci. 2008 Jul-Aug;421:241-3.
**Zozulya AA, et al. The inhibitory effect of selank on enkephalin-degrading enzymes as a possible mechanism of its anxiolytic activity.** Bull Exp Biol Med. 2001 Apr;131(4):315-7.

- Selank increases BDNF in rats
- Selank have been found to inhibit enzymes involved in the degradation of enkephalins (which may be the mechanism of action for the anxiolytic activity)

Anxiolytics

# Selank affects Gene expression

Volkova A, et. al., Selank Administration Affects the Expression of Some Genes Involved in GABAergic Neurotransmission. Front Pharmacol. 2016 Feb 18;7:31.

- Study on Rats
- Three hours after Selank administration, 22 genes changed their expression of GABAergic system (transporter of GABA and GABA receptors)

# Dosing of Selank

- Selank has a poor oral deliverly
- Can be delivered by Subcutaneous or intranasal

- Suggested dosing
- 75 µg of Selank per nasal spray. The recommended dosage is 1-2 sprays per dose with 2- 3 doses per day (a max total of 675 µg/day)

# Nootropic agent

- Substance that enhances cognition and memory and facilitates learning
- Cerebrolysin
- Semax
- Selank
- TB4

# Thymsoin Beta 4 was discovered in the 1970's

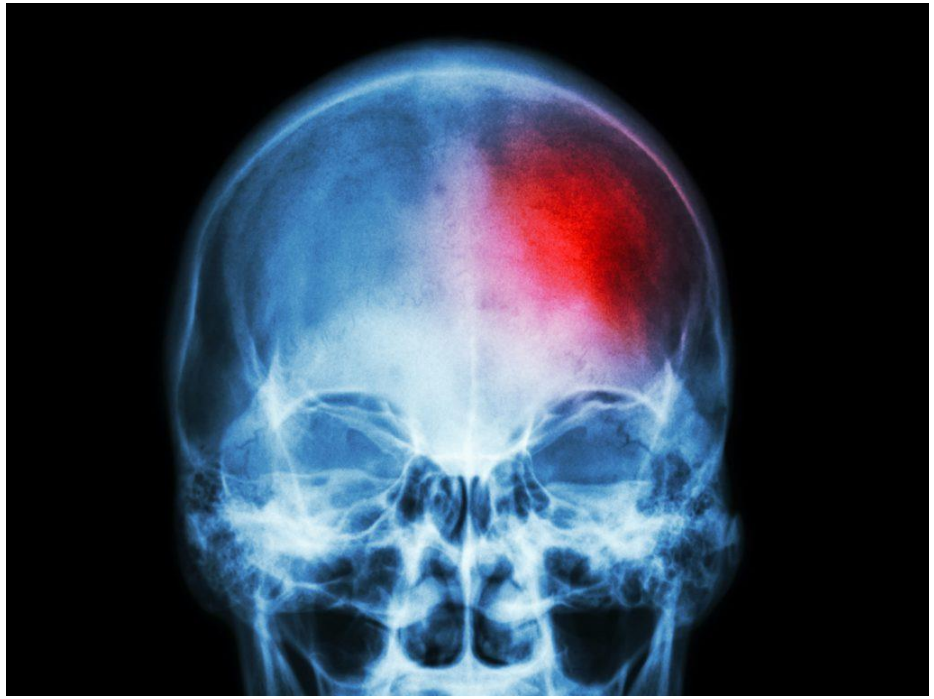
- TB4 expressed in nearly all cells
- TB4 is 43-amino acid peptide
- TB4 is a pleiotropic peptide that has multifaceted restorative properties.

- In 2010, Thymosin Beta 4 was given intravenously as a single dose or in multiple daily doses for 14 days over a dose range of 42-1260 mg was well tolerated with no evidence toxicity
- Ruff D, et al. Ann N Y Acad Sci. 2010 Apr;1194:223-9

# Thymsoin Beta 4 (TB4)

Michael Chopp & Zheng Gang Zhang (2015) Thymosin β4 as a restorative/ regenerative therapy for neurological injury and neurodegenerative diseases, Expert Opinion on Biological Therapy, 15:sup1, 9-12

- TB4 has been used in animal models to treat stroke, TBI, intracerebral hemorrhage and diabetic peripheral neuropathy

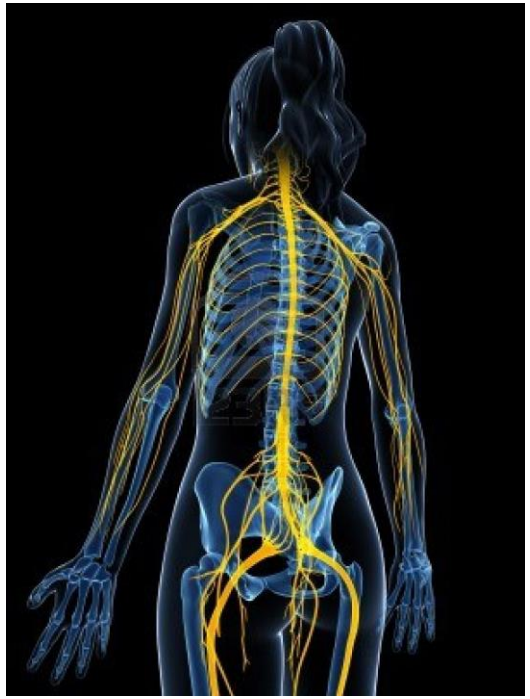


# Thymsoin Beta 4 (TB4) myelination

Michael Chopp & Zheng

Gang Zhang (2015) Thymosin β4 as a restorative/ regenerative therapy for neurological injury and neurodegenerative diseases, Expert Opinion on Biological Therapy, 15:sup1, 9-12

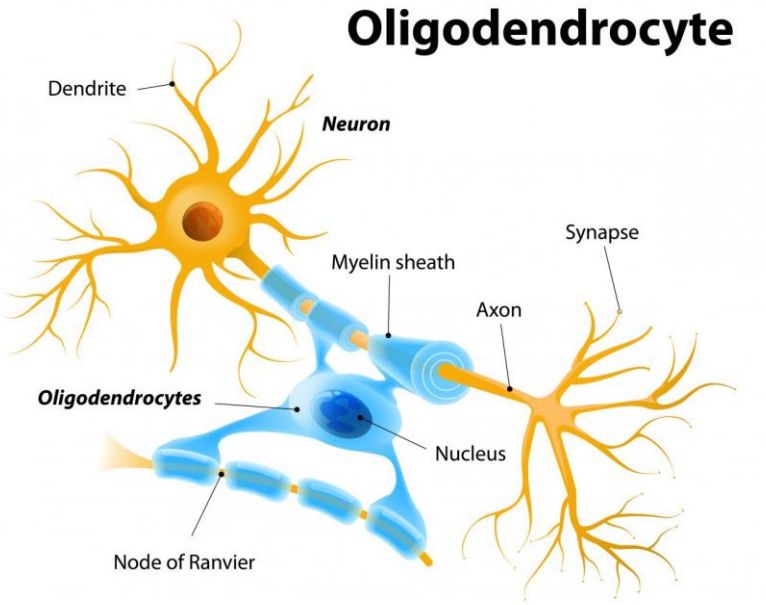
- Thymosin B4 promotes CNS and peripheral nervous system (PNS) myelination.



# Thymsoin Beta 4 (TB4) How does it work Michael Chopp & Zheng

Gang Zhang (2015) Thymosin β4 as a restorative/ regenerative therapy for neurological injury and neurodegenerative diseases, Expert Opinion on Biological Therapy, 15:sup1, 9-12

- An important common thread by which TB4 weaves neurological recovery in multiple disease and injury states is by stimulating oligodendrocytes (OLGs), OLG progenitor cells (OPCs) and myelination.

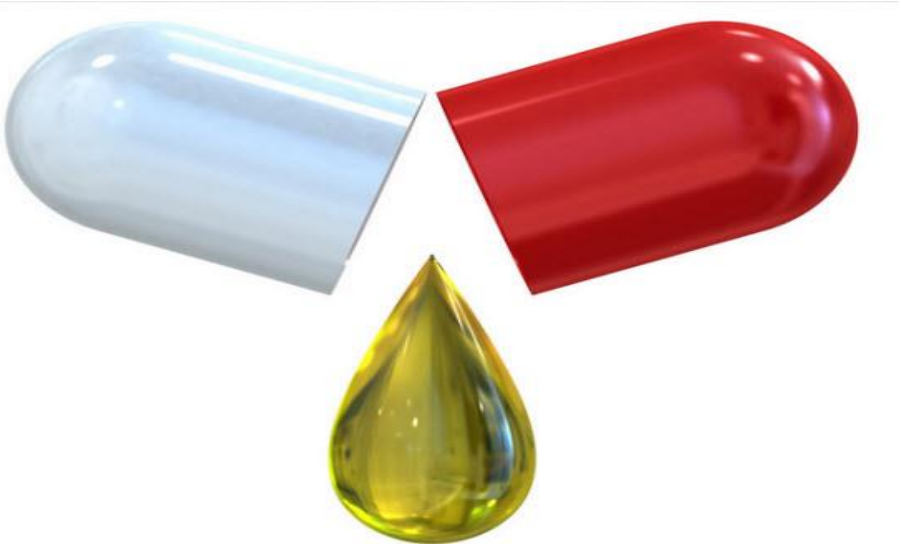


# Thymsoin Beta 4 (TB4) conclusion

- TB4 is neuroprotective and also neuroregenerative
- Anti inflammatory
- Increase in Oligodendrocytes
- Increase in myelination
- No human clinical trials for neuroregeration done yet

# Dosing of Thymsoin Beta 4

- Comes in  3000 mcg/ml
- Can give it SQ or IV Push
- For acute injury –IVP push 2.5 ml ( 7.5 mg ) mixed in 5 cc of NSS push over 5 minutes
- SQ daily to 1.5 mg ( ½ cc ) BID for 3-5 days
- Reduce it to ¼ cc or 750 mcg SQ daily  for 20- 30 days
- Brooksville Rx compounding – 352-848-3466



# What happens if you can't get TB4

- Thymosin beta 4 frag
- It is the bioactive part of TB4
- 4 amino acid vs 43 AA
- Acetyl-N-Ser-Asp-Lsy-Pro (AcSDKP)

- Comes in a pill – 500 mcg a day

# TB4 frag

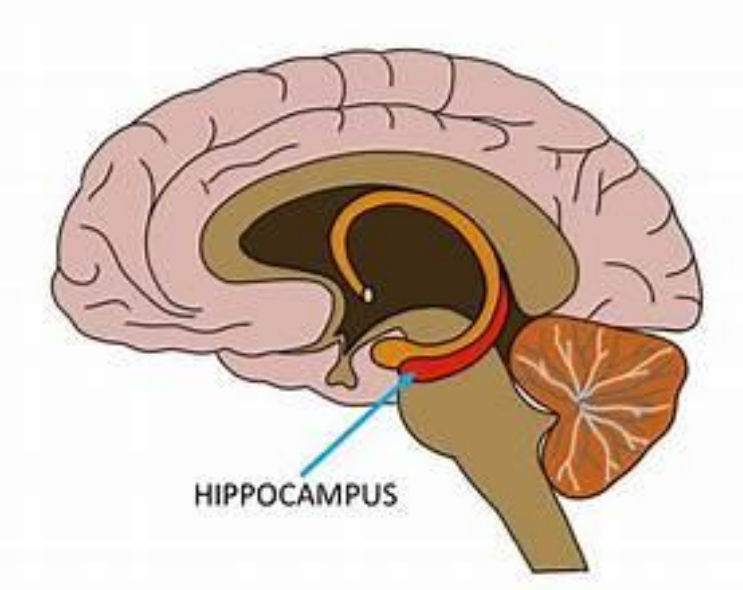
Neuroscience. 2015 Dec 3:310:51-62. doi: 10.1016/j.neuroscience.2015.09.017. Epub 2015 Sep 9.

## Peptide fragment of thymosin β4 increases hippocampal neurogenesis and facilitates spatial memory

D H Kim [1], E-Y Moon [2], J H Yi [3], H E Lee [4], S J Park [4], Y-K Ryu [5], H-C Kim [6], S Lee [7], J H Ryu [8]

Kim DH, et al., Peptide fragment of thymosin β4 increases hippocampal neurogenesis and facilitates spatial memory. Neuroscience. 2015 Dec 3;310:51-62

- Mice study
- Intrahippocampal infusion of TB4 frag facilitated the generation of new neurons in the hippocampus



Kim DH, et al., Peptide fragment of thymosin β4 increases hippocampal neurogenesis and facilitates spatial memory. Neuroscience. 2015 Dec 3;310:51-62

- Intrahippocampal infusion of TB4 frag also increased spatial memory.
- TB4 frag may be a therapeutic candidate for diseases characterized by neuronal loss.

Cavasin MA. Therapeutic potential of thymosin-beta4 and its derivative N-acetyl-seryl-aspartyl-lysyl-proline (Ac-SDKP) in cardiac healing after infarction. Am J Cardiovasc Drugs. 2006;6(5):305-11.

- TB4 facilitates cardiac repair after infarction by promoting cell migration and myocyte survival.
- TB4 frag has been shown in animal studies to reduce LV fibrosis in hypertensive rats, reverse fibrosis and inflammation in rats with MI and stimulate in vivo angiogenesis.

# Conclusion of Nootropic agents

- Cerebrolysin increases BDNF, stimulates stem cells
- Semax increases BDNF
- Selank increases BDNF
- TB4 increases myelination


MARVEL
WOLVERINE HEALING FACTOR

# BPC 157 (Healing Peptide)

- BPC is a 15 amino acid peptide
- BPC is an acronym for ‘Body Protection Compound’
- Also referred to as PL 14736, PL-10 or Bepecin

# Published In Alternative Therapies Jul/Aug 2021 vol 27 no 4.

> Altern Ther Health Med. 2021 Jul;27(4):8-13.

## Intra-Articular Injection of BPC 157 for Multiple Types of Knee Pain

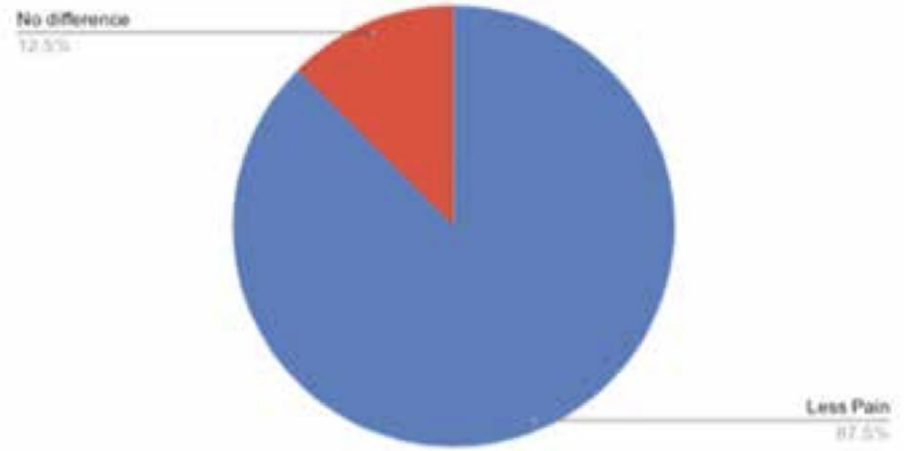
Edwin Lee, Blake Padgett

PMID: 34324435

# Study of BPC157 in knee pain

Lee, E. Intra-Articular Injection of BPC157for multiple types of knee pain. Alternative Therapies Jul/Aug 2021 vol 27 no 4.

**Figure 1.** Overall pain in all 16 patients; 14 out of 16 (87.5%) had improvement in knee pain.

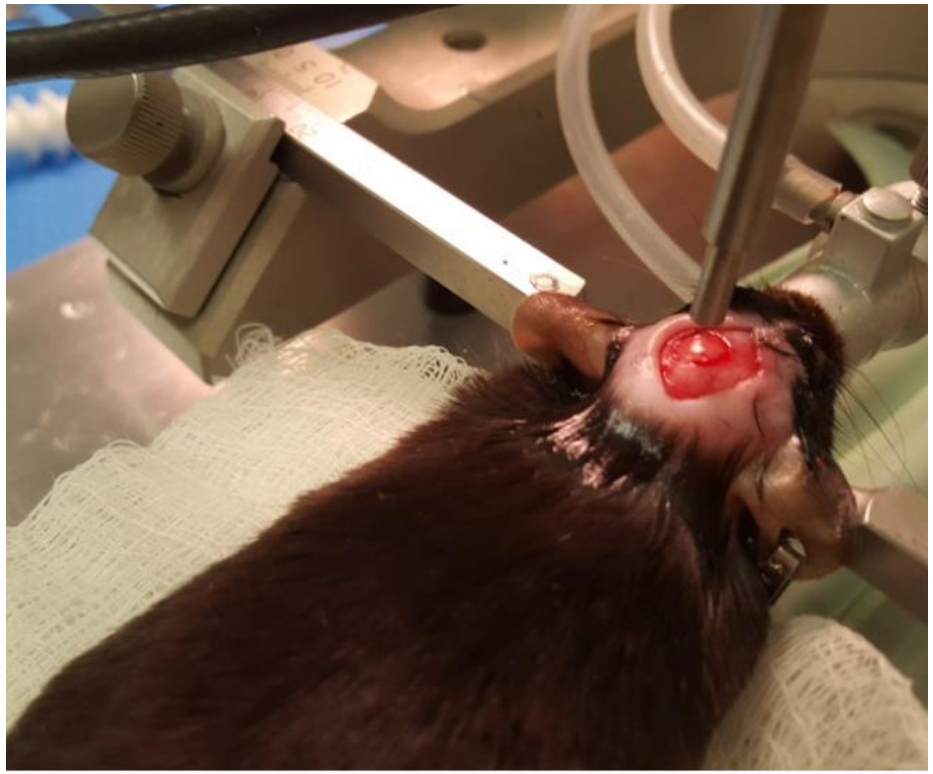



- BPC157 is a non-FDA approved peptide that has regenerative properties.
- 14/16 had improvement in knee pain.

# BPC 157 in TBI in rats

Tudor M, et al. Traumatic brain injury in mice and pentadecapeptide BPC 157 effect. Regul Pept. 2010 Feb 25;160(1-3):26-32

- Induce TBI in mice by a falling weight
- BPC 157 given 30 min prior
- Subarachnoidal and intraventricular haemorrhage, brain laceration were less intense with BPC 157



Integrative Healthcare SYMPOSIUM

# Make Your Voice Heard

Help us Save Peptides from the FDA.

Help us protect our rights to medical freedom.

Sign Petition

# On 9/2023 the FDA listed these 22 peptides on the 503A category 2 or category 3

| AOD-9604 | DSIP |
|---|---|
| ARA 290 | Epitalon |
| BPC157 | GHK-Cu (injection) |
| LL-37 | GHRP-6 |
| CJC-1295 | Ibutamoren (MK667) |
| Dihexa | |

| Ipamorelin | Selank |
|---|---|
| Kisspeptin -10 | Semax |
| KPV | TA1 |
| Melanotan 2 | TB4 |
| PEG-MGF | Thymulin |
| MOTS-c | |

Dinetz E, Lee E. Comprehensive Review of the Safety and Efficacy of Thymosin Alpha 1 in Human Clinical Trials. Altern Ther Health Med. 2024 Jan;30(1):6-12. PMID: 38308608.

REVIEW ARTICLE

# Comprehensive Review of the Safety and Efficacy of Thymosin Alpha 1 in Human Clinical Trials

Elliot Dinetz, MD; Edwin Lee, MD

Dinetz E, Lee E. Comprehensive Review of the Safety and Efficacy of Thymosin Alpha 1 in Human Clinical Trials. Altern Ther Health Med. 2024 Jan;30(1):6-12. PMID: 38308608.

**Table 1.** Safety Trials on Tα1 for Various Infectious Diseases (8075 Patients)

| Author | Description | Sample Size | Adverse Effects |
|---|---|---|---|
| Shang et al. 2023[5] | Analysis of multiple studies on the effectiveness of Tα1 treatment for COVID-19. | 5352 | No allergic reactions or drug eruptions |
| Tuthill et al. 2023[4] | Application of Tα1 to patients on hemodialysis coinciding with COVID-19 infection. | 194 | No differences between the Tα1 group and placebo group with serious adverse effects |
| Wang et al. 2021[10] | Tα1 treatment in hospitalized patients with COVID-19. | 275 | No side effects were noted |
| Li et al. 2021[61] | Gender-specific markers in COVID-19 infected patients treated with Tα1. | 127 | No side effects were noted |
| Wu et al. 2013[11] | Tα1 for severe sepsis: a multicenter, single-blind, randomized and controlled trial | 361 | No Tα1 severe adverse event was reported |
| Liu et al. 2016[62] | Review of randomized controlled trials on Tα1 treatment in sepsis | 530 | No reported severe adverse event or treatment discontinuation with Tα1 |
| Andreone et al. 1996[17] | Tα1 for the treatment of chronic hepatitis C | 19 | No side effects were noted |
| Rasi et al. 1996[18] | Tα1 and interferon for the treatment of chronic hepatitis C | 15 | No side effects were noted |
| Moscarella et al. 1998[19] | Tα1 and interferon for the treatment of chronic hepatitis C | 17 | No side effects were noted |
| Sherman et al. 1998[22] | Tα1 and interferon for the treatment of chronic hepatitis C | 35 | No side effects were noted |
| Ciancio et al, 2012[20] | Tα1 with peginterferon alfa-2a/ribavirin for chronic hepatitis C not responsive to IFN/ribavirin: | 275 | No side effects were noted |
| Poo et al. 2008[23] | Tα1 with peginterferon alfa-2a and ribavirin for chronic hepatitis C not responsive to IFN/ribavirin | 40 | No side effects were noted |
| You et al. 2006[13] | Tα1 and interferon-alpha in the treatment of chronic viral hepatitis B | 62 | 3 patients had local site irritation. . .No other side effects were reported |
| Peng et al. 2020[14] | Meta-analysis on Tα1 plus Entecavir in Hepatitis B cirrhosis | 572 | Entecavir plus Tα1 led to a significant decrease in adverse events compared with monotherapy. |
| Lin et al. 2002[63] | Tα1 and famciclovir in chronic Hepatitis B | 32 | No side effects were noted |
| Zhang et al. 2009[16] | Meta-analysis on Tα1 plus Lamivudine in chronic Hepatitis B | 295 | No side effects were noted |
| Ramachandran et al. 1996[24] | Tα1, interleukin-2, and zidovudine in HIV | 12 | No side effects were noted |
| Garaci et al. 1998[25] | A randomized controlled study of zidovudine, thymosin-α1 and interferon-α in HIV | 92 | No side effects were noted |
| Chadwick et al. 2003[26] | Thymosin alpha 1 in augmenting immune reconstitution in HIV-infected patients with low CD4 counts taking highly active antiretroviral therapy | 13 | No side effects were noted |
| | Total Number of Patients: 8318 | | |

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**Table 2.** Safety Trials on Tα1 for Cancer Treatment (2742 Patients)

| Author | Description | Sample Size | Adverse Effects |
|---|---|---|---|
| Linye et al. 2021[64] | Tα1 therapy with Hepatitis B related hepatocellular carcinoma | 468 | No side effects were noted |
| Shuqun et al. 2004[45] | Combination transcatheter hepatic arterial chemoembolization with Tα1 on recurrence prevention of hepatocellular carcinoma | 18 | No adverse effects were reported. |
| Liang et al. 2016[44] | Tα1 therapy subsequent to radical hepatectomy in patients with hepatitis B virus-associated hepatocellular carcinoma | 146 | No adverse effects were reported |
| Stefanini et al. 1998[46] | Tα1 and Transcatheter arterial chemoembolization in hepatocellular carcinoma | 12 | No side effects were noted |
| Shuqun et al. 2006[65] | Tα1 and lamivudine for Hepatitis B associated hepatocellular carcinoma | 16 | No adverse effects were reported |
| Lopez et al. 1994[39] | Tα1, interleukin-2 and dacarbazine therapy in metastatic melanoma | 46 | No side effects were noted |
| Rasi et al. 2000[66] | Tα1, interleukin-2 and dacarbazine therapy in metastatic melanoma | 20 | No side effects were noted |
| Maio et al. 2010[41] | Phase 2 trial with Tα1 Dacarbazine with or without interferon-alpha for stage 4 melanoma | 488 | No adverse effects were reported. |
| Danielli et al. 2018[42] | Tα1 therapy with immune checkpoint Ab in metastatic melanoma | 61 | No adverse effects were reported. Follow up for more than 4 years |
| Schulof et al. 1985[29] | Randomized trial of Tα1 in non-small cell lung cancer | 42 | No adverse effects were reported. |
| Garaci et al. 1995[30] | Phase 2 trial with Tα1 and chemoimmunotherapy for advanced non-small cell lung cancer | 56 | Overall, treatment was well tolerated |
| Salvati et al. 1996[31] | Phase 2 trial with Tα1 and low dose interferon alpha after ifosfamide in non-small cell lung cancer | 22 | Hematologic toxicity was reduced with Tα1 |
| Jiang et al. 2011[32] | Meta-analysis Tα1 plus cisplatin with vinorelbine or gemcitabine for non-small cell lung cancer | 320 | No drug-related serious adverse events |
| Guo et al. 2021[34] | Long-term survival with Tα1 therapy with non-small cell lung cancer after margin-free resected surgery | 1027 | No drug-related serious adverse events and no adverse events that led to Tα1 discontinuation |
| Dou et al. 2011[35] | Patients with invasive ductal carcinoma were evaluated in 2 groups, one receiving hormonal therapy and the other 4 cycles of chemotherapy, where all received Tα1 | 36 | There are side effects from a depressed immune system, including less pain |
| Wenbo et al. 2023[67] | A prospective randomized controlled study of conventional and high dose Tα1 plus chemotherapy compared to chemotherapy alone | 200 | no discontinuation of treatment with reduced incidence of postoperative complications |
| An et al. 2004[36] | Clinical trial of Tα1 with chemotherapy for patients with colorectal cancer to reduce neurotoxicity | 22 | Tα1 reduced the neurotoxicity side effects with chemotherapy |

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