

Thymosin Alpha-1 — Research Summary

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1. What It Is

Thymosin Alpha-1 (Tα1) is a naturally occurring 28-amino-acid thymic peptide that modulates innate and adaptive immunity via Toll-like receptors (TLR2/3/4/7/9), activating IRF3 and NF-κB signaling pathways in T cells, B cells, macrophages, and NK cells.

Unlike most compounds in this set, a synthetic version (thymalfasin) is an approved pharmaceutical product in over 35 countries (though not FDA-approved in the U.S.) for chronic viral hepatitis and as an immune adjunct.

2. Reported Effects in Research Literature

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- Human data: A Phase III multicenter, randomized, double-blind, placebo-controlled trial (97 patients) evaluated Tα1 for chronic hepatitis B, comparing complete-response rates against placebo over 12 months.
- Human data: A multicenter randomized controlled trial (ETASS) evaluated Tα1 as adjunctive therapy for severe sepsis across six tertiary hospitals, assessing 28-day all-cause mortality.
- Human data: A systematic review/meta-analysis of 5 RCTs (706 patients) evaluated Tα1 for immune regulation in severe acute pancreatitis.
- Human data: Multiple RCTs and meta-analyses have evaluated Tα1 combined with antivirals (entecavir, lamivudine, interferon, famciclovir) for chronic hepatitis B.

3. Clinical & Preclinical Study References

Tao N, Xu X, Ying Y, et al. Thymosin α1 and Its Role in Viral Infectious Diseases: The Mechanism and Clinical Application. *Molecules*. 2023;28(8):3539. PMC10144173

Mutchnick MG, et al. Thymosin alpha1 treatment of chronic hepatitis B: results of a phase III multicentre, randomized, double-blind and placebo-controlled study. PMID: 10607256

Li C, Bo L, Liu Q, Jin F. Thymosin alpha1 based immunomodulatory therapy for sepsis: a systematic review and meta-analysis. *Int J Infect Dis*. 2015;33:90-96. PMID: 25532482

The efficacy of thymosin alpha 1 for severe sepsis (ETASS): a multicenter, single-blind, randomized and controlled trial. PMC4056079

Regulatory/Safety Note: Thymalfasin (synthetic Tα1) is approved in 35+ countries but has never received FDA approval in the United States; U.S.-sold research-labeled Tα1 is not the approved pharmaceutical product.

This compound has not been evaluated by the FDA and is not intended to diagnose, treat, cure, or prevent any disease in humans or animals.

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