



THYMALFASIN (THYMOSIN ALPHA 1) WITH TRANS ARTERIAL CHEMOEMBOLIZATION (TACE) IN THE TREATMENT OF ADULT PATIENTS WITH UNRESECTABLE HEPATOCELLULAR CARCINOMA: A PHASE II TRIAL

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ABSTRACT

BACKGROUND:

Surgical resection or liver transplantation are the standards of care for patients with early stages of hepatocellular carcinoma (HCC); however, most patients present with advanced unresectable HCC. For patients with advanced HCC, transarterial chemoembolization (TACE) is a reliable palliative treatment, but prognosis remains poor. The addition of cancer immunotherapy may improve outcomes for this patient population.

Thymalfasin (thymosin alpha 1; T α 1) is a 28-amino acid peptide that stimulates the production of T cells and Th1 cytokines and blocks T-cell apoptosis. Thymalfasin also has direct anti-cancer effects, which may be effective in combination with TACE treatment.

OBJECTIVE:

The objective of this study was to compare the efficacy and safety of thymalfasin plus TACE vs TACE alone in patients with unresectable HCC.

METHODS:

This randomized, controlled, multicenter, US study included 25 patients who had unresectable HCC. Patients received 24 weeks of either 1.6 mg thymalfasin 5 times a week plus TACE or TACE alone. Following treatment, patients were monitored regularly for up to 2 years. Efficacy parameters included tumor response by RECIST criteria, survival, changes in α -fetoprotein (AFP), and performance status.

RESULTS:

The median survival time was 994 days for patients randomized to treatment with thymalfasin plus TACE compared with a median survival of 399 days for patients treated with TACE alone ($P=0.44$). No thymalfasin-related adverse events were reported. Nineteen patients reported a total of 37 serious adverse events, including 6 deaths.

CONCLUSION:

There was a trend toward increased survival among HCC patients treated with the combination of thymalfasin and TACE, which validated the need for a large phase III trial to further evaluate the survival and tumor response capabilities of this treatment regimen.

BASELINE PATIENT CHARACTERISTICS

	ZADAXIN Plus TACE (n=14)	TACE Alone (n=11)	P Value
Median age	62	60	0.721
Gender			0.660
Male	10 (71.4%)	9 (81.8%)	
Female	4 (28.6%)	2 (18.2%)	
AFP			0.340
n	7	9	
Mean	7150.36	10325.8	
Range	9.20 to 35545.4	5.70 to 74818.0	
Okuda status			0.836
n	14	11	
Mean	1.36	1.36	
Range	0.00 to 3.00	1.00 to 2.00	
ALT			0.326
n	9	10	
Mean	102.22	75.60	
Range	35.00 to 202.00	20.00 to 139.00	
AST			0.153
n	9	10	
Mean	115.33	86.80	
Range	68.00 to 208.00	45.00 to 150.00	

MEDIAN SURVIVAL TIME INCREASED WHEN THYMALFASIN WAS ADDED TO TACE THERAPY

