



Effect of Tesamorelin in People with HIV with and without dorsocervical fat: Post Hoc analysis of Phase III double blind placebo control trial

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Background

Lipohypertrophy is excess fat deposition in abdominal visceral adipose tissue (VAT), dorsocervical region, breasts, trunk, and other areas. Multiple factors may contribute to lipohypertrophy in people with HIV (PWH), including patient characteristics, antiretroviral therapy (ART) and impaired growth hormone secretion. Tesamorelin, a synthetic form of growth-hormone-releasing hormone, is indicated for reduction of excess abdominal fat in PWH with lipodystrophy.

Methods

Post-hoc analysis was done on phase 3 randomized, double-blind, multicenter trials. Patients were eligible if between 18 and 65 years old, had confirmed HIV infection, had evidence of excess abdominal fat accumulation and on stable ART regimen for 8 weeks or more. Participants were randomized to receive tesamorelin 2 mg daily or placebo daily for 26 weeks. Only tesamorelin responders, defined as patients with at least 8% decrease in VAT and who were adherent to the medication, were used for this analysis.

Results

Table 1: Baseline Characteristics of Tesamorelin Responder Subjects, by Dorsocervical Status

Variable	Main phase (26 weeks)		P value
	With Dorsocervical Fat (N=88)	Without Dorsocervical Fat (N=144)	
Sex, n (%)			
Male	75 (85.2)	128 (88.9)	0.37
Age (years)			
N	88	144	
mean (SD)	48.0 (6.8)	47.4 (7.1)	0.63
CD4 Cell count (cells/mm³)			
n	88	144	
mean (SD)	658.4 (296.69)	578.4 (279.85)	0.071
Viral Load, n (%)			
Undetectable	72 (81.8)	108 (75.0)	0.16
BMI			
n	88	144	
Mean (SD)	29.68 (4.17)	27.68 (3.25)	<0.001
Presence of Lipoatrophy, n (%)			
Yes	70 (79.5)	101 (70.1)	0.16
Waist Circumference (cm)			
N	88	144	
mean (SD)	105.99 (9.95)	102.32 (7.39)	0.002
VAT (cm²)			
N	88	144	
mean (SD)	189.68 (87.04)	184.88 (78.59)	0.57
VAT:SAT			
N	86	142	
mean (SD)	1.075 (0.98)	1.40 (1.61)	0.10

Table 2: Change in Metabolic Parameters Between Baseline and Week 26 Among Tesamorelin Responder Patients with and without Dorsocervical Fat

Variable	Patients with Dorsocervical Fat (n=88)				Patients without Dorsocervical Fat (n=144)			
	Baseline	Week 26	Change	P-value within group	Baseline	Week 26	Change	P value within group
VAT (cm²)								
N	88	88	88		144	144	144	
mean (SD)	189.68 (87.04)	139.67 (67.95)	-50.01 (33.13)	<0.001	184.88 (78.59)	134.65 (69.21)	-50.23 (33.95)	<0.001
SAT (cm²)								
N	85	85	85		142	142	142	
mean (SD)	246.77 (126.95)	243.22 (119.41)	-3.56 (42.02)	0.44	204.00 (107.68)	192.72 (101.42)	-11.28 (31.11)	<0.001
Waist Circumference (cm)								
N	88	88	88		143	143	143	
mean (SD)	105.99 (9.95)	102.37 (10.18)	-3.62 (6.35)	<0.001	102.35 (7.41)	97.77 (9.12)	-4.58 (5.24)	<0.001
Lean Mass (kg)								
N	83	83	83		143	143	143	
mean (SD)	62.97 (9.64)	64.25 (10.24)	1.29 (2.08)	<0.001	61.75 (9.55)	63.54 (9.72)	1.79 (2.59)	<0.001

At week 26, on average, the patients with dorsocervical fat deposition had higher BMI and waist circumference (WC) than the group without dorsocervical fat. Most patients in both groups had lipoatrophy. There was a decrease in VAT and an improvement in their WC at week 26 in both with and without dorsocervical fat groups, however a reduction in subcutaneous adipose tissue (SAT) was only seen in those without dorsocervical fat.

Conclusions

This data demonstrates that tesamorelin is effective at reducing VAT in both patients with and without dorsocervical fat. Treatment of excessive VAT with tesamorelin has seemingly positive results in fat reduction in patients with or without dorsocervical fat deposition and our study contributes to the growing literature.