

Orlistat 60 mg demonstrates a significant reduction in visceral adipose tissue at 24 weeks compared with placebo

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Aims To determine whether a 24 week weight loss program with orlistat 60mg plus diet will produce a greater reduction from baseline in visceral adipose tissue (VAT) mass compared to placebo plus diet in overweight and obese subjects.

Methods: This study was a 24 week, multicenter, randomized, double-blind, placebo controlled study. Overweight and obese subjects (BMI 25-35.0 kg/m²) with a waist circumference >88 cm (women) or 102 cm (men) were randomized to receive orlistat 60mg or placebo, 3 times per day along with recommendations to follow a reduced calorie, low-fat diet and encouraged to exercise. Body weight was measured at baseline and weeks 2, 4, 8, 12, 16, 20, and 24. VAT was measured by multi-slice abdominal CT scanning at baseline and at week 24.

Results: 123 subjects were randomized, treated and had at least one post-baseline assessment. Demographic and baseline characteristics were similar between orlistat 60mg (N=62) and placebo (N=61).

Table 1. Mean Change in VAT (kg) from Baseline to Week 24

Treatment Group	N	Baseline Mean	Mean Change (% Change) Baseline to Week 24	p-value
Placebo	54	4.023	-0.403 (-9.39%)	<0.0001
Orlistat	55	3.807	-0.630 (-15.66%)	<0.0001
Difference (Placebo – Orlistat)			0.227	0.0244

Both groups had a significant decrease in VAT from baseline to week 24; however, the mean reduction in VAT was significantly greater in the orlistat-treated group (Table 1). For European interest, a post-hoc analysis among those with BMI_≥28 showed a similar trend in the VAT reduction difference between treatment groups (p=0.105).

Additionally, there was a significant reduction in mean body weight from baseline to week 24 in both orlistat- and placebo-treated subjects (-5.96kg and -3.91kg, respectively), but a significantly greater body weight loss was observed in the orlistat group (p<0.05).

Conclusion: Orlistat 60mg plus diet results in significantly greater weight loss in overweight and obese individuals with increased waist circumference, and importantly, a significantly greater reduction in visceral fat as compared to placebo plus diet alone following treatment for 24 weeks.