

# Clinical trials of Orlistat

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## 1 obesity and overweight

Trial	Treatments	Patients	Trials design and methods
<b>Orlistat vs placebo</b>			
<b>Bakris , 2002</b> n=278/276 follow-up: 1-year	orlistat versus placebo	obese individuals with inadequately controlled hypertension.	double-blind
<b>Broom , 2002</b> n=265/261 follow-up: 54-week	orlistat versus placebo	obese patients with cardiovascular risk	parallel group double-blind
<b>Broom, , 2001</b> n=71/71 follow-up:	-	-	
<b>Davidson , 1999</b> n=668/224 follow-up: 52 weeks	orlistat, 120 mg 3 times a day, for 52 weeks versus placebo	Obese adults (BMI 30-43 kg/m2)	double-blind US
<b>Deerochanawong, , 2001</b> n=126/126 follow-up:	-	-	
<b>Derosa , 2003</b> n=27/23 follow-up: 1-year	orlistat 120 mg TID versus placebo	obese patients with hypercholesterolemia	double-blind
<b>Gotfredsen , 2001</b> n=16/14 follow-up:	-	-	
<b>Halpern , 2003</b> n=169/174 follow-up: 24 weeks	orlistat (120 mg t.i.d.), versus placebo	Obese, non-insulin-dependent diabetic patients, aged 18-70 years old, with BMI >27 kg/m2	paralle Double-blind Latin-America
<b>Hanefeld , 2002</b> n=195/188 follow-up: 48-week	orlistat 120 mg t.i.d. versus placebo	Overweight or obese adults (BMI >or= 28 kg/m2) with HbA1c of 6.5-11% and clinical type 2 diabetes	double-blind

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
Hauptman , 2000 n=210/212 follow-up: 1 year	60 mg of orlistat TID or 120 mg of orlistat TID, versus placebo	obese patients (BMI 30-44 kg/m <sup>2</sup> )	double-blind USA
Hill , 1999 n=181/188 follow-up: 1 year	30 mg orlistat, 60 mg orlistat, or 120 mg orlistat 3 times daily for 1 y versus placebo	Obese subjects who lost $\geq 8\%$ of their initial body weight during a 6-mo lead-in of a prescribed hypoenergetic diet (4180-kJ/d deficit) with no adjunctive pharmacotherapy	double-blind
Hollander , 1998 n=163/159 follow-up: 57-week	120 mg orlistat orally three times a day versus placebo	obese men and women with type 2 diabetes who were aged $>18$ years, had a BMI of 28-40 kg/m <sup>2</sup> , and were clinically stable on oral sulfonylureas	double-blind
Karhunen , 2000 n=36/36 follow-up: 1 y.	orlistat 120 mg t.i.d. versus placebo	obese subjects	double-blind
Kelley , 2002 n=274/276 follow-up: 1-year	orlistat 120 mg three times a day versus placebo	overweight or obese adults (BMI 28-40 kg/m <sup>2</sup> ) with type 2 diabetes treated with insulin alone or combined with oral agents, but with suboptimal metabolic control (HbA <sub>1c</sub> 7.5-12.0% )	double-blind
Krempf , 2005 n=346/350 follow-up: 18-month	orlistat 120 mg three times daily versus placebo	otherwise healthy, overweight patients aged 18-65 y (BMI $\geq 28$ kg/m <sup>2</sup> )	double-blind
Lindgarde , 2000 n=190/186 follow-up: 1 year	orlistat 120 mg three times daily versus placebo	obese adults (body mass index 28-38 kg m-2) with type 2 diabetes, hypercholesterolaemia and/or hypertension	double-blind Sweden
Lucas , 2003 n=256/188 follow-up:	-	-	
Micic , 1999 n=60/59 follow-up: 24 weeks	orlistat 120 mg three times daily versus placebo	obese patients (BMI $\geq 30$ kg/m <sup>2</sup> ) with hyperlipidemia (LDL-cholesterol $\geq 4, 2$ mmol/l)	double-blind
Miles , 2002 n=255/261 follow-up: 1 year	120 mg orlistat t.i.d. versus placebo	overweight and obese patients with suboptimal control of type 2 diabetes	double-blind

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
Muls , 2001 n=147/147 follow-up: 24 week	orlistat 120 mg three times daily versus placebo	obese hypercholesterolemic patients, BMI between 27-40 kg/m <sup>2</sup> and low-density-lipoprotein cholesterol, LDL-C, between 4.1-6.7 mmol/l	double-blind
Naumov , 2002 n=15/15 follow-up:	orlistat versus diet alone	patients with stable angina pectoris concomitant with obesity and hyperlipemia	open
Reaven , 2001 n=156/91 follow-up:	-	-	
Rissanen , 2001 n=25/26 follow-up: 12-month	orlistat 120 mg three times daily versus placebo	healthy obese women	double-blind
Rosenfalck , 2002 n=3/1 follow-up:	-	obese patients	
Rossner , 2000 n=244/243 follow-up: 2-year	orlistat (60 or 120 mg) three times a day versus Obese patients (body mass index 28 to 43 kg/m <sup>2</sup> )	Obese patients (body mass index 28 to 43 kg/m <sup>2</sup> )	double-blind
Shi Yi , 2001 n=986/142 follow-up:	-	-	
Sjostrom , 1998 n=345/343 follow-up: 1 year	-	-	double-blind Europe
Vidgren , 1999 n=37/38 follow-up: 1 year	120 mg of orlistat three times a day versus placebo	obese subjects	

More details and results :

- All mechanism for obesity and overweight in all type of patients at <http://www.trialresultscenter.org/go-Q265>

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## 2 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
<b>orlistat vs placebo</b>			
<b>Heymsfield , 2000</b> n=359/316 follow-up: 4 weeks	orlistat 120 mg three times/day versus placebo	obese (body mass index, 30-43 kg/m <sup>2</sup> ) adults (WHO 1985 criteria)	Parallel groups double blind USA, Europe
<b>XENDOS (Chiasson) , 2002</b> n=714/715 follow-up: 3 months	orlistat 120 mg three times/day versus placebo	patients with impaired glucose tolerance (WHO 1994)	Parallel groups double blind Sweden

More details and results :

- prevention for diabetes type 2 in all type of patients at <http://www.trialresultscenter.org/go-Q341>
- prevention for diabetes type 2 in people with impaired glucose tolerance at <http://www.trialresultscenter.org/go-Q416>

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