

Clinical trials of Orlistat

TrialResults-center www.trialresultscenter.org

1 obesity and overweight

Trial	Treatments	Patients	Trials design and methods
Orlistat vs placebo			
Bakris , 2002 n=278/276 follow-up: 1-year	orlistat versus placebo	obese individuals with inadequately controlled hypertension.	double-blind
Broom , 2002 n=265/261 follow-up: 54-week	orlistat versus placebo	obese patients with cardiovascular risk	parallel group double-blind
Broom, , 2001 n=71/71 follow-up:	-	-	
Davidson , 1999 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
Deerochanawong, , 2001 n=126/126 follow-up:	-	-	
Derosa , 2003 n=27/23 follow-up: 1-year	orlistat 120 mg TID versus placebo	obese patients with hypercholesterolemia	double-blind
Gotfredsen , 2001 n=16/14 follow-up:	-	-	
Halpern , 2003 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
Hanefeld , 2002 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...

Trial	Treatments	Patients	Trials design and methods
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 ²)	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 ² , 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 ²) with type 2 diabetes treated with insulin alone or combined with oral agents, but with suboptimal metabolic control (HbA _{1c} 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 ≥ 28 kg/m ²)	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 ≥ 30 kg/m ²) 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...

Trial	Treatments	Patients	Trials design and methods
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 ² 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 ²)	Obese patients (body mass index 28 to 43 kg/m ²)	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>

References

Bakris, 2002:

Bakris G, Calhoun D, Egan B, Hellmann C, Dolker M, Kingma I Orlistat improves blood pressure control in obese subjects with treated but inadequately controlled hypertension. J Hypertens 2002 Nov;20:2257-67 [12409965]

Broom, 2002:

Broom I, Wilding J, Stott P, Myers N Randomised trial of the effect of orlistat on body weight and cardiovascular disease risk profile in obese patients: UK Multimorbidity Study. *Int J Clin Pract* 2002 Sep;56:494-9 [[12296610](#)]

Broom,, 2001:

Broom I. Randomised trial of the effect of orlistat on body weight and CVD risk profile in overweight and obese patients with co-morbidities [Abstract]. *Int J Obes*. 2001;25 Suppl:S106

Davidson, 1999:

Davidson MH, Hauptman J, DiGirolamo M, Foreyt JP, Halsted CH, Heber D, Heimbürger DC, Lucas CP, Robbins DC, Chung J, Heymsfield SB Weight control and risk factor reduction in obese subjects treated for 2 years with orlistat: a randomized controlled trial. *JAMA* 1999 Jan 20;281:235-42 [[9918478](#)]

Deerochanawong,, 2001:

Deerochanawong C. Effect of treatment with orlistat in overweight or obese Thai patients with type 2 diabetes [Abstract]. *Diabetes*. 2001;50:A433.

Derosa, 2003:

Derosa G, Mugellini A, Ciccarelli L, Fogari R Randomized, double-blind, placebo-controlled comparison of the action of orlistat, fluvastatin, or both an anthropometric measurements, blood pressure, and lipid profile in obese patients with hypercholesterolemia prescribed a standardized diet. *Clin Ther* 2003 Apr;25:1107-22 [[12809960](#)]

Gotfredsen, 2001:

Reaven G, Segal K, Hauptman J, Boldrin M, Lucas C Effect of orlistat-assisted weight loss in decreasing coronary heart disease risk in patients with syndrome X. *Am J Cardiol* 2001 Apr 1;87:827-31 [[11274935](#)]

Halpern, 2003:

Halpern A, Mancini MC, Suplicy H, Zanella MT, Repetto G, Gross J, Jadzinsky M, Barranco J, Aschner P, Ramirez L, Matos AG Latin-American trial of orlistat for weight loss and improvement in glycaemic profile in obese diabetic patients. *Diabetes Obes Metab* 2003 May;5:180-8 [[12681025](#)]

Hanefeld, 2002:

Hanefeld M, Sachse G The effects of orlistat on body weight and glycaemic control in overweight patients with type 2 diabetes: a randomized, placebo-controlled trial. *Diabetes Obes Metab* 2002 Nov;4:415-23 [[12406041](#)]

Hauptman, 2000:

Hauptman J, Lucas C, Boldrin MN, Collins H, Segal KR Orlistat in the long-term treatment of obesity in primary care settings. *Arch Fam Med* 2000 Feb;9:160-7 [[10693734](#)]

Hill, 1999:

Hill JO, Hauptman J, Anderson JW, Fujioka K, O'Neil PM, Smith DK, Zavoral JH, Aronne LJ Orlistat, a lipase inhibitor, for weight maintenance after conventional dieting: a 1-y study. *Am J Clin Nutr* 1999 Jun;69:1108-16 [[10357727](#)]

Hollander, 1998:

Hollander PA, Elbein SC, Hirsch IB, Kelley D, McGill J, Taylor T, Weiss SR, Crockett SE, Kaplan RA, Comstock J, Lucas CP, Lodewick PA, Canovatchel W, Chung J, Hauptman J Role of orlistat in the treatment of obese patients with type 2 diabetes. A 1-year randomized double-blind study. *Diabetes Care* 1998 Aug;21:1288-94 [[9702435](#)]

Karhunen, 2000:

Karhunen L, Franssila-Kallunki A, Rissanen P, Valve R, Kolehmainen M, Rissanen A, Uusitupa M Effect of orlistat treatment on body composition and resting energy expenditure during a two-year weight-reduction programme in obese Finns. *Int J Obes Relat Metab Disord* 2000 Dec;24:1567-72 [[11126207](#)]

Kelley, 2002:

Kelley DE, Bray GA, Pi-Sunyer FX, Klein S, Hill J, Miles J, Hollander P Clinical efficacy of orlistat therapy in overweight and obese patients with insulin-treated type 2 diabetes: A 1-year randomized controlled trial. *Diabetes Care* 2002 Jun;25:1033-41 [[12032111](#)]

Krempf, 2005:

Krempf M, Louvet JP, Allanic H, Miloradovich T, Joubert JM, Attali JR Weight reduction and long-term maintenance after 18 months treatment with orlistat for obesity. *Int J Obes Relat Metab Disord* 2003 May;27:591-7 [[12704403](#)]

Lindgarde, 2000:

Lindgarde F The effect of orlistat on body weight and coronary heart disease risk profile in obese patients: the Swedish Multimorbidity Study. *J Intern Med* 2000 Sep;248:245-54 [[10971792](#)]

Lucas, 2003:

Lucas CP, Boldrin MN, Reaven GM Effect of orlistat added to diet (30

Micic, 1999:

Micic D, Ivkovic-Lazar T, Dragojevic R, Jorga J, Stokic E, Hajdukovic Z Orlistat, a gastrointestinal lipase inhibitor, in therapy of obesity with concomitant hyperlipidemia. *Med Pregl* 1999 Sep-Oct;52:323-33 [[10624380](#)]

Miles, 2002:

Miles JM, Leiter L, Hollander P, Wadden T, Anderson JW, Doyle M, Foreyt J, Aronne L, Klein S Effect of orlistat in overweight and obese patients with type 2 diabetes treated with metformin. *Diabetes Care* 2002 Jul;25:1123-8 [[12087008](#)]

Muls, 2001:

Muls E, Kolanowski J, Scheen A, Van Gaal L The effects of orlistat on weight and on serum lipids in obese patients with hypercholesterolemia: a randomized, double-blind, placebo-controlled, multicentre study. *Int J Obes Relat Metab Disord* 2001 Nov;25:1713-21 [[11753595](#)]

Naumov, 2002:

Naumov VG, Lupanov VP, Dotsenko IuV, Tvorogova MG [Six-month xenical (orlistat) therapy of patients with stable angina pectoris concomitant with obesity and hyperlipidemia] *Ter Arkh* 2002;74:47-51 [[11878059](#)]

Reaven, 2001:

Reaven G, Segal K, Hauptman J, Boldrin M, Lucas C Effect of orlistat-assisted weight loss in decreasing coronary heart disease risk in patients with syndrome X. *Am J Cardiol* 2001 Apr 1;87:827-31 [[11274935](#)]

Rissanen, 2001:

Rissanen P, Vahtera E, Krusius T, Uusitupa M, Rissanen A Weight change and blood coagulability and fibrinolysis in healthy obese women. *Int J Obes Relat Metab Disord* 2001 Feb;25:212-8 [[11410822](#)]

Rosenfalck, 2002:

Rosenfalck AM, Hendel H, Rasmussen MH, Almdal T, Anderson T, Hilsted J, Madsbad S Minor long-term changes in weight have beneficial effects on insulin sensitivity and beta-cell function in obese subjects. *Diabetes Obes Metab* 2002 Jan;4:19-28 [[11890163](#)]

Rossner, 2000:

Rossner S, Sjostrom L, Noack R, Meinders AE, Nosedo G Weight loss, weight maintenance, and improved cardiovascular risk factors after 2 years treatment with orlistat for obesity. *European Orlistat Obesity Study Group. Obes Res* 2000 Jan;8:49-61 [[10678259](#)]

Shi Yi, 2001:

Shi Yi F, Zhu Jun R. Effect of orlistat on weight loss and glycemic control in overweight Chinese patients with type 2 diabetes [Abstract]. *Diabetes*. 2001;50:A101-A102

Sjostrom, 1998:

Sjostrom L, Rissanen A, Andersen T, Boldrin M, Golay A, Koppeschaar HP, Krempf M Randomised placebo-controlled trial of orlistat for weight loss and prevention of weight regain in obese patients. *European Multicentre Orlistat Study Group. Lancet* 1998 Jul 18;352:167-72 [[9683204](#)]

Vidgren, 1999:

Vidgren HM, Agren JJ, Valve RS, Karhunen LJ, Rissanen AM, Uusitupa MI The effect of orlistat on the fatty acid composition of serum lipid fractions in obese subjects. *Clin Pharmacol Ther* 1999 Sep;66:315-22 [[10511068](#)]

2 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
orlistat vs placebo			
Heymsfield , 2000 n=359/316 follow-up: 4 weeks	orlistat 120 mg three times/day versus placebo	obese (body mass index, 30-43 kg/m ²) adults (WHO 1985 criteria)	Parallel groups double blind USA, Europe
XENDOS (Chiasson) , 2002 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>

References

Heymsfield, 2000:

Heymsfield SB, Segal KR, Hauptman J, Lucas CP, Boldrin MN, Rissanen A, Wilding JP, Sjstrm L Effects of weight loss with orlistat on glucose tolerance and progression to type 2 diabetes in obese adults. Arch Intern Med 2000;160:1321-6 [10809036]

XENDOS (Chiasson), 2002:

Chiasson JL, Josse RG, Gomis R, Hanefeld M, Karasik A, Laakso M Acarbose for prevention of type 2 diabetes mellitus: the STOP-NIDDM randomised trial. Lancet 2002;359:2072-7 [12086760] 10.1016/S0140-6736(02)08905-5

Torgerson JS, Hauptman J, Boldrin MN, Sjstrm L XENical in the prevention of diabetes in obese subjects (XENDOS) study: a randomized study of orlistat as an adjunct to lifestyle changes for the prevention of type 2 diabetes in obese patients. Diabetes Care 2004;27:155-61 [14693982]

Entry terms: orlistat, orlistat, tetrahydrolipstatin, THLP, Alli, Xenical,