Clinical trials of prevention for diabetes type 2 in all type of patients

TrialResults-center www.trialresultscenter.org

1 alpha-glucosidase inhibitor

Trial	Treatments	Patients	Trials design and methods
error vs placebo			
Pan , 2003 n=261 follow-up: 16 weeks	acarbose 50 mg three times daily versus placebo	patients with impaired glucose tolerance (American Diabetes Association 1997 criteria)	Parallel groups double blind China
STOP-NIDDM (Chiasson) , 2002 n=714/715 follow-up: 3.3 years	acarbose 100mg three times daily versus placebo	patients with impaired glucose tolerance (WHO 1985 criteria)	Parallel groups double blind Canada, Germany, Austria, Nordic countries, Spain, Israel
voglibose vs placebo			
Voglibose Ph-3 , 2009 [UMIN 000001109-] n=897/881 follow-up: 4.01 years	voglibose 0.2 mg three times daily versus placebo	patients with impaired fasting glucose	Parallel groups double blind Japan

References

Pan, 2003:

Pan CY, Gao Y, Chen JW, Luo BY, Fu ZZ, Lu JM, Guo XH, Cheng H Efficacy of acarbose in Chinese subjects with impaired glucose tolerance. Diabetes Res Clin Pract 2003;61:183-90 [12965108]

STOP-NIDDM (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]

Chiasson JL, Josse RG, Gomis R, Hanefeld M, Karasik A, Laakso M Acarbose treatment and the risk of cardiovascular disease and hypertension in patients with impaired glucose tolerance: the STOP-NIDDM trial. JAMA 2003;290:486-94 [12876091]

Voglibose Ph-3, 2009:

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Kawamori R, Tajima N, Iwamoto Y, Kashiwagi A, Shimamoto K, Kaku K Voglibose for prevention of type 2 diabetes mellitus: a randomised, double-blind trial in Japanese individuals with impaired glucose tolerance. Lancet 2009;373:1607-14 [19395079]

2 angiotensin receptor blocker

Trial	Treatments	Patients	Trials design and methods
valsartan vs placebo			
NAVIGATOR valsartan , 2010 [NCT00097786] n=4631/4675 follow-up: 5 years	valsartan up to 160 mg daily versus placebo	subjects with impaired glucose tolerance and either CV disease or CV risk factors	Factorial plan double-blind 40 countries

References

NAVIGATOR valsartan, 2010:

Effect of Valsartan on the Incidence of Diabetes and Cardiovascular Events. N Engl J Med 2010 Mar 16;: [20228403] 10.1056/NEJMoa1001121

Krum H, McMurray JJ, Horton E, Gerlock T, Holzhauer B, Zuurman L, Haffner SM, Bethel MA, Holman RR, Califf RM Baseline characteristics of the Nateglinide and Valsartan Impaired Glucose Tolerance Outcomes Research (NAVIGATOR) trial population: comparison with other diabetes prevention trials. Cardiovasc Ther 2010;28:124-32 [20184589] 10.1111/j.1755-5922.2010.00146.x

3 angiotensin-converting enzyme inhibitors

Trial	Treatments	Patients	Trials design and methods
ramipril vs placebo			
DREAM ramipril , 2006 [NCT00095654] n=2623/2646 follow-up: 3 y (median)	ramipril up to 15 mg daily versus placebo	patients with impaired fasting glucose or impaired glucose tolerance, or both, and no previous cardiovascular disease	Parallel groups double blind 21 countries

References

DREAM ramipril, 2006:

4 anti-obesity agents

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/m2) adults (WHO 1985 criteria)	Parallel groups double blind USA, Europe

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Trial	Treatments	Patients	Trials design and methods
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

References

Heymsfield, 2000:
XENDOS (Chiasson), 2002:

5 antidiabetic drugs

Trial	Treatments	Patients	Trials design and methods
metformin vs control			
James , 2005 n=10/10 follow-up: 8 weeks	metformin 1 g BID versus no treatment	Abdominal obesity with insulin resistance[	
glipizide vs placebo			
Eriksson , 2006 n=34 follow-up: 18 months	glipizide 2.5 mg daily versus placebo	first-degree relatives of patients with type 2 diabetes fulfilling WHO criteria for IGT (WHO criteria in 2006)	Parallel groups double blind Finland
metformin vs placebo			
Baillargeon , 2004 n=32/32 follow-up: 26 weeks	metformin 850 mg BID versus placebo	Non obese women with PCOS	
Bridger , 2006 n=11/11 follow-up: 12 weeks	metformin 750 mg BID versus placebo	Adolescents with PCOS and insulin resistance	
Charles , 1998 n=227/230 follow-up: 52 weeks	metformin 850 mg BID versus placebo	Abdominal obesity	
Charles , 2000 n=83/85 follow-up: 13 weeks	metformin 850 mg BID versus placebo	Abdominal obesity, hypertension, and elevated triglycerides	
Choux , 2003 n=15/17 follow-up: 13 weeks	metformin 500 mg TID versus placebo	PCO	
Crave , 1995 n=12/12 follow-up: 17 weeks	metformin 850 mg BID versus placebo	Overweight with PCO	

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Trial	Treatments	Patients	Trials design and methods
EDIT (Holman) , 2003 n=631 follow-up:	metformin 500 mg three times/day, versus placebo	(WHO 1985 criteria)	UK
Fleming , 2002 n=45/47 follow-up: 17 weeks	metformin 850 mg BID versus placebo	PCO	
Freemark , 2001 n=16/16 follow-up: 26 weeks	metformin 500 mg BID versus placebo	Insulin resistance and family history of diabetes	
Gambineri , 2004 n=10/10 follow-up: 26 weeks	metformin 850 mg BID versus placebo	Obesity and PCOS	
Giugliano , 1993 n=12/12 follow-up: 12 weeks	metformin 850 mg BID versus placebo	Hypertension with normal glucose tolerance	
Hoeger , 2004 n=18/20 follow-up: 48 weeks	metformin 850 mg BID + lifestyle modification versus placebo + lifestyle modification	Overweight with PCOSo[	
Kay , 2001 n=12/12 follow-up: 8 weeks	metformin 850 mg BID versus placebo	Adolescents with morbid obesity	
Kelly , 2002 n=16/16 follow-up: 26 weeks	metformin 500 mg TID versus placebo	PCO	
Kocak , 2002 n=28/28 follow-up: 8 weeks	metformin 850 mg BID versus placebo	PCO	
Lehtovirta , 2001 n=20/20 follow-up: 26 weeks	metformin 500 mg BID versus placebo	Overweight with impaired glucose tolerance and family history of diabetes	
Li , 1999 n=33/37 follow-up: 12 months	metformin 250 mg three times/day versus placebo	patients with impaired glucose tolerance (WHO 1985 criteria)	Parallel groups double blind China
Moghetti , 2000 n=12/11 follow-up: 26 weeks	metformin 500 mg TID versus placebo	PCOS with normal glucose tolerance	
Morel , 1999 n=19/19 follow-up: 8 weeks	metformin 850 mg BID versus placebo	Impaired glucose tolerancee	
Ng , 2001 n=10/10 follow-up: 12 weeks	metformin 500 mg TID versus placebo	PCO	

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Trial	Treatments	Patients	Trials design and methods
Orchard , 2005 n=1073/1082 follow-up: 156 weeks	metformin 850 mg BID versus placebo	Impaired glucose tolerance	
Pasquali , 2000 n=20/20 follow-up: 26 weeks	metformin 850 mg BID versus placebo	Abdominal obesity with and without PCO	
Rodriguez , 2004 n=10/11 follow-up: 20 weeks	metformin 1.7 g/d versus placebo	Obesity with insulin resistance	
Rodriguez-Moctezuma , 2004 n=12/11 follow-up: 8 weeks	metformin 850 mg BID versus placebo	Family history of diabetes	
Sirtori , 1984 n=15/15 follow-up: 26 weeks	metformin 850 mg BID versus placebo	Peripheral vascular disease	
Srinivasan , 2006 n=28/28 follow-up: 26 weeks	metformin 1 g BID versus placebo	Children and adolescents with obesity and insulin resistance	
Stakos , 2005 n=59/97 follow-up: 104 weeks	metformin 500 mg/d versus placebo	African-Americans with insulin resistance and family history of diabetes	
Sturrock , 2002 n=17/17 follow-up: 13 weeks	metformin 1500 mg/d versus placebo	PCO	
Tang , 2006 n=69/74 follow-up: 26 weeks	metformin 850 mg BID versus placebo	Obesity with PCO	
US-DPP (metformin) (Knowler) , 2002 n=3234 follow-up: 2.8 years	metformin 850mg twice daily versus placebo	nondiabetic patients with elevated glucose and high risk for diabetes	Parallel groups double blind USA
Vitale , 2005 n=32/33 follow-up: 13 weeks	metformin 500 mg BID versus placebo	Metabolic syndrome	
nateglinide vs placebo			
NAVIGATOR nateglinide , 2010 [NCT00097786] n=4645/4661 follow-up: 5 years	nateglinide 60mg 3 times daily versus placebo	subjects with impaired glucose tolerance and either CV disease or CV risk factors	Factorial plan double-blind 40 countries
rosiglitazone vs placebo			
DREAM rosiglitazone , 2006 [NCT00095654] n=2365/2634 follow-up: 3 years (median)	rosiglitazone 8 mg daily versus placebo	patients with impaired fasting glucose or impaired glucose tolerance, or both	Parallel groups double blind 21 countries

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Trial	Treatments	Patients	Trials design and methods
troglitazone vs placebo			
TRIPOD (Buchanan) , 2002 n=133/133 follow-up: 30 months (median)	troglitazone 400 mg once daily versus placebo	Hispanic women with previous gestational diabetes	Parallel groups double blind USA
US DDP troglitazone (Knowler) , 2005 n=585/582 follow-up: 0.9 year	troglitazone versus double placebo	nondiabetic patients with elevated glucose and high risk for diabetes	Parallel groups double blind USA

References

James, 2005:
Eriksson, 2006:
Baillargeon, 2004:
Bridger, 2006:
Charles, 1998:
Charles, 2000:
Choux, 2003:
Crave, 1995:
EDIT (Holman), 2003:
Fleming, 2002:
Freemark, 2001:
Gambineri, 2004:
Giugliano, 1993:
Hoeger, 2004:
Kay, 2001:
Kelly, 2002:
Kocak, 2002:
Lehtovirta, 2001:
Li, 1999:
Moghetti, 2000:
Morel, 1999:
Ng, 2001:
Orchard, 2005:
Pasquali, 2000:
Rodriguez, 2004:
Rodriguez-Moctezuma, 2004:
Sirtori, 1984:
Srinivasan, 2006:
Stakos, 2005:
Sturrock, 2002:

Tang, 2006:
US-DPP (metformin) (Knowler), 2002:
Vitale, 2005:
NAVIGATOR nateglinide, 2010:
DREAM rosiglitazone, 2006:
TRIPOD (Buchanan), 2002:
US DDP troglitazone (Knowler), 2005:

6 drugs + lifestyle modification

Trial	Treatments	Patients	Trials design and methods
lifestyle modification + metformin vs control			
IDDP (Ramachandran) , 2006 n=531 follow-up: 2.5 y	advice on lifestyle modification, metformin, or both versus given standard health care advice (control)	native Asian Indians with impaired glucose tolerance	Parallel groups open India
Jarret , 1979 n=204 follow-up: 4.3 y	carbohydrate restriction with phenformin 50 mg daily versus carbohydrate restriction alone	men with impaired glucose toleranc	Parallel groups open

References

IDDP (Ramachandran), 2006:
Jarret, 1979:

7 glitazones

Trial	Treatments	Patients	Trials design and methods
rosiglitazone and metformin vs placebo			
CANOE , 2010 [NCT00116932] n=103/104 follow-up: 3.9y (median)	rosiglitazone (2 mg) and metformin (500 mg) twice-daily versus placebo	patients with impaired glucose tolerance	Parallel groups double-blind

References

CANOE, 2010:

8 herbal preparation

Trial	Treatments	Patients	Trials design and methods
jiangtang bushen recipe vs control			
Fan , 2004 n=51 follow-up: 4.1 y	jiangtang bushen recipe 2-3 times/week versus placebo	patients with impaired glucose tolerance (WHO 1999 criteria)	Parallel groups open China

References

Fan, 2004:

9 insulin

Trial	Treatments	Patients	Trials design and methods
insulin glargine vs placebo			
GRACE - ORIGIN (glargine) , 2012 n=1184 follow-up:	insulin glargine (with a target fasting blood glucose level of <=95 mg per deciliter [5.3 mmol per liter]) versus standard glycemic care alone	subject with known CV disease and/or CV risk factors plus impaired fasting glucose, impaired glucose tolerance, or type 2 diabetes	Factorial plan open-label

References

GRACE - ORIGIN (glargine), 2012:

10 lifestyle modification

Trial	Treatments	Patients	Trials design and methods
AHA 2 diet vs AHA 1 diet			

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Trial	Treatments	Patients	Trials design and methods
Liao , 2002 n=70 follow-up: 22 months	American Heart Association (AHA) step 2 diet (<30% of total calories as fat, <7% saturated fat, 55% carbohydrate, and <200 mg cholesterol daily) plus endurance exercise for 1 h three times a week versus AHA step 1 diet (30% of total calories as fat, 10% saturated fat, 50% carbohydrate, and <300 mg cholesterol) plus stretching exercise three times a week	Japanese American subjects with impaired glucose tolerance (WHO criteria 1998)	Parallel groups open USA
lifestyle modification vs control			
DPS (Lindstrm) , 2003 n=522 follow-up: 3.2y	individualized counseling aimed at reducing weight and intake of total and saturated fat, and increasing intake of fiber and physical activity versus control	Patients overweight with impaired glucose tolerance (WHO 1985 criteria)	Parallel groups open Finnish
Fang , 2004 n=178 follow-up:	-	subject with impaired glucose tolerance	Parallel groups China
JDPP (Sakane) , 2005 n=240 follow-up:	-	patients with impaired glucose tolerance (WHO 1999 criteria)	Parallel groups Japan
Keen , 1982 n=241 follow-up:	-	subject with impaired glucose tolerance	Parallel groups
Kosaka , 2005 n=356/102 follow-up: 3.64 y	to maintain body mass index (BMI) of <24.0 kg/m2 and of <22.0 kg/m2, respectively, by diet and exercise. In the intervention group, detailed instructions on lifestyle were repeated every 3-4 months versus control	men with impaired glucose tolerance (WHO criteria 1980)	Parallel groups open Japan
Pan , 1997 n=530 follow-up: 6 y	three active treatment groups: diet only, exercise only, or diet plus exercise versus control	Patients with impaired glucosetolerance (WHO 1985 criteria)	Parallel groups open China
Tao , 2004 n=60 follow-up: 31 months	-	patients with impaired glucose tolerance (WHO 1999 criteria)	Parallel groups China
US-DDP (lifestyle) (Knowler) , 2002 n=1079/1082 follow-up: 2.8 years	lifestyle-modification intervention versus placebo	nondiabetic patients with elevated glucose and high risk for diabetes	Parallel groups open
intensive dietary advice vs routine dietary advice			

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Trial	Treatments	Patients	Trials design and methods
Wein , 1999 n=200 follow-up: 4.24 y	intensive dietary advice versus routine dietary advice	women with previous gestational diabetes and currently with impaired glucose tolerance (WHO 1985 criteria)	Parallel groups open USA

References

Liao, 2002:
DPS (Lindstrm), 2003:
Fang, 2004:
JDPP (Sakane), 2005:
Keen, 1982:
Kosaka, 2005:
Pan, 1997:
Tao, 2004:
US-DDP (lifestyle) (Knowler), 2002:
Wein, 1999:

11 n-3 fatty acid supplement

Trial	Treatments	Patients	Trials design and methods
n-3 fatty acid supplement vs placebo			
GRACE - ORIGIN (n-3 fatty acid) n=1184 follow-up: 4.9y (median)	n-3 fatty acid supplemen versus placebo	subjects with known CV disease and/or CV risk factors plus impaired fasting glucose, impaired glucose tolerance, or type 2 diabetes	Factorial plan double-blind

References

GRACE - ORIGIN (n-3 fatty acid), :

12 About TrialResults-center.org

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