

Clinical trials of antiplatelets drug for diabetes type 2 in patients without cardiovascular disease

TrialResults-center www.trialresultscenter.org

1 platelet aggregation inhibitors

| Trial | Treatments | Patients | Trials design and methods |
|--------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| aspirin vs no treatment | | | |
| PPP (diabetics sub group) , 2003 n=519/512 follow-up: 3.6 y | aspirin 100mg daily versus control | men and women with diabetes and without a previous cardiovascular event aged >50 with >=1 risk factors for cardiovascular disease - sub group of diabetic patients | Factorial plan open Italy |
| JPAD , 2008 [NCT00110448] n=1262/1277 follow-up: 4.37 y median | low-dose aspirin (81 or 100 mg per day) versus no aspirin | patients with type 2 diabetes without a history of atherosclerotic disease | Parallel groups open Japan |
| aspirin vs placebo | | | |
| PHS (diabetics sub group) , 1989 n=275/258 follow-up: 5 y | aspirin 325 mg every other day versus placebo | healthy men (diabetic sub group of patients enrolled if PHS) | Factorial plan double blind |
| ETDRS , 1992 n=1856/1855 follow-up: 60 months | aspirin 650mg once daily versus placebo | patients with diabetes mellitus (Type I or II) | Parallel groups double blind |
| WHS (diabetics sub group) , 2005 n=514/513 follow-up: 10.1 y | aspirin 100mg on alternate days versus placebo | healthy women 45 years of age or older - diabetics sub groups | Parallel groups double blind US |
| POPADAD aspirin , 2008 [ISRCTN53295293] n=638/638 follow-up: nov 1997 - jul 2001 | aspirin 100mg daily versus placebo | patients with diabetes mellitus and asymptomatic peripheral arterial disease | Factorial plan double blind Scotland |
| DAMAD , 1989 n=318/157 follow-up: 3 y | aspirin alone (330 mg 3 times daily) or in combination with dipyridamole (75 mg 3 times daily) versus placebo | patients with early diabetic retinopathy | Parallel groups double blind |
| ASCEND (aspirin) ongoing [NCT00135226] n=NA follow-up: | aspirin 100mg daily versus placebo | people with diabetes without cardiovascular disease | Factorial plan double blind UK |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|----------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| ACCEPT-D <i>ongoing</i> [ISRCTN48110081] n=NA follow-up: | aspirin 100mg daily top simvastatin 20mg daily versus no aspirin on top simvastatin 20mg daily | diabetic patients without clinically manifest vascular disease | Parallel groups open |
| picotamide vs placebo | | | |
| Cocozza , 1995 n=25/25 follow-up: 24 months | picotamide 300 mg TID versus placebo | normotensive diabetic patients with asymptomatic mild or moderate nonstenotic (<50%) carotid atherosclerotic lesions and negative history of cerebrovascular ischemic events | Parallel groups double blind Italy |
| sulfinyrazone vs placebo | | | |
| Dutch , 1980 <i>unpublished</i> n=30/31 follow-up: 32 months | - | - | Parallel groups |
| ticlopidine vs placebo | | | |
| Birmingham-A , 1979 <i>unpublished</i> n=20/8 follow-up: 2 months | - | - | Parallel groups |
| London diabetes , 1983 <i>unpublished</i> n=38/40 follow-up: 12 months | - | - | Parallel groups |
| TIMAD , 1984 n=220/215 follow-up: 32m | - | - | Parallel groups |
| BTRS , 1992 n=49/51 follow-up: 48 months | ticlopidine 500mg/d versus placebo | insulin-treated diabetics with background retinopathy | Parallel groups double blind |
| Nyberg , 1984 n=12/11 follow-up: 12 months | ticlopidine 500mg daily versus placebo | insulin dependent diabetes complicated by nephropathy | Parallel groups double blind |

References

PPP (diabetics sub group), 2003:

Sacco M, Pellegrini F, Roncagliani MC, Avanzini F, Tognoni G, Nicolucci A Primary prevention of cardiovascular events with low-dose aspirin and vitamin E in type 2 diabetic patients: results of the Primary Prevention Project (PPP) trial. *Diabetes Care* 2003;26:3264-72 [[14633812](#)]

JPAD, 2008:

Ogawa H, Nakayama M, Morimoto T, Uemura S, Kanauchi M, Doi N, Jinnouchi H, Sugiyama S, Saito Y Low-dose aspirin for primary prevention of atherosclerotic events in patients with type 2 diabetes: a randomized controlled trial. *JAMA* 2008;300:2134-41 [[18997198](#)]

PHS (diabetics sub group), 1989:

Final report on the aspirin component of the ongoing Physicians' Health Study. Steering Committee of the Physicians' Health Study Research Group. *N Engl J Med* 1989;321:129-35 [[2664509](#)]

ETDRS, 1992:

Aspirin effects on mortality and morbidity in patients with diabetes mellitus. Early Treatment Diabetic Retinopathy Study report 14. ETDRS Investigators. JAMA 1992 Sep 9;268:1292-300 [[1507375](#)]

WHS (diabetics sub group), 2005:

Ridker PM, Cook NR, Lee IM, Gordon D, Gaziano JM, Manson JE, Hennekens CH, Buring JE A randomized trial of low-dose aspirin in the primary prevention of cardiovascular disease in women. N Engl J Med 2005;352:1293-304 [[15753114](#)] [10.1056/NEJMoa050613](#)

POPADAD aspirin, 2008:

Belch J, MacCuish A, Campbell I, Cobbe S, Taylor R, Prescott R, Lee R, Bancroft J, MacEwan S, Shepherd J, Macfarlane P, Morris A, Jung R, Kelly C, Connacher A, Peden N, Jamieson A, Matthews D, Leese G, McKnight J, O'Brien I, Semple C, Petrie J, Gordon D, The prevention of progression of arterial disease and diabetes (POPADAD) trial: factorial randomised placebo controlled trial of aspirin and antioxidants in patients with diabetes and asymptomatic peripheral arterial disease. BMJ 2008 Oct 16;337:a1840 [[18927173](#)]

DAMAD, 1989:

ASCEND (aspirin), 0:

ACCEPT-D, 0:

Cocozza, 1995:

Dutch, 1980:

Birmingham-A, 1979:

London diabetes, 1983:

TIMAD, 1984:

BTRS, 1992:

Nyberg, 1984:

3

2 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

TrialResults-center is non-profit and self-funded.