

**Evidence Tables**  
**PREV 1: Does aspirin prevent vascular disease in people with type 2 diabetes?**

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Effect size	Source of funding
P. Khajehdehi, J. Roozbeh, and H. Mostafavi. A comparative randomized and placebo-controlled short-term trial of aspirin and dipyridamole for overt type-2 diabetic nephropathy. <i>Scandinavian Journal of Urology &amp; Nephrology</i> 36 (2):145-148, 2002.	RCT  1+	N=76	Inclusion criteria: type 2 diabetes, nephropathy (proteinuria $\geq 500\text{mg/day}$ ), normal renal function tests, well controlled BP and blood sugar, not receiving ACE inhibitors  Exclusion criteria: serum creatinine $>2\text{mg/dL}$ , blood urea nitrogen $>20\text{mg/dL}$ , bacteriuria, recurrent or relapsing UTIs, haematuria and/or pyuria  There were no significant differences in the 4 groups at randomisation	N=19 aspirin 1,000mg  N=19 combination of aspirin (1,000mg) and dipyridamole (750mg)	N=19 dipyridamole 750mg  N=19 placebo	2 months	Proteinuria, urinary protein:creatinine ratio, BP, renal function, blood sugar <sup>1</sup>	*Proteinuria There was a significant decrease in proteinuria with the treatment groups compared with placebo; aspirin proteinuria change was -15.9%, dipyridamole -14.8%, the combination -37.3% and placebo showed an increase of 1.9%, $p=0.0007$ .  *Urinary protein:creatinine ratio There was a significant decrease with the 3 treatment groups compared with placebo  *Blood pressure, renal function tests and blood sugar results were unchanged.  *Adverse events No side effects related to aspirin and dipyridamole was noted during the study.	Not stated
M. Sacco, F. Pellegrini, M. C. Roncaglioni, F. Avanzini, G.	RCT, open label, multi centre	N=1,031 with diabetes (from overall	Inclusion criteria: diabetes, fasting venous plasma glucose $\geq 7.8\text{mmol/L}$ on two	N=519 100mg aspirin per day	N=509 300mg vitamin E per day	3.7yrs (study terminated early, was planned to	Incidence of major cardiovascular and	In diabetic participants changes with aspirin were NS. In the overall study in nondiabetic participants there was a significant reduction in the main	Co-ordination expense

<sup>1</sup> The authors state that to the best of their knowledge this is the first clinical trial of aspirin in type-2 diabetic nephropathy.

<p>Tognoni, A. Nicolucci, and PPP Collaborative Group. 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.[see comment]. <i>Diabetes Care</i> 26 (12):3264-3272, 2003.</p>	<p>1+</p>	<p>study sample of N=4,784)  N=4,495 control group</p>	<p>separate occasions or treated with antidiabetic drugs, ≥50yrs, without history of major cardiovascular events.</p> <p>Exclusion criteria: severe pathology, treatment with antiplatelet drugs, chronic use of anti-inflammatory agents or anticoagulants, chronic use of aspirin or vitamin E, contra-indications to aspirin, disease with poor short-term prognosis</p> <p>Patient characteristics were similar and use of antidiabetic and lipid-lowering drugs were well balanced, across the groups. Though there was a higher percentage of subjects with hypertension and hypercholesterolaemia in the aspirin group</p>			<p>be 5 years, on the recommendation of the independent data safety and monitoring board when newly available evidence on the benefit of aspirin in primary prevention was available)</p>	<p>cerebrovascular events, included cardiovascular deaths, total deaths, total cardiovascular events</p>	<p>combined end point, total cardiovascular events, cardiovascular deaths and peripheral artery disease, with aspirin.</p> <p>There were no significant changes with vitamin E in either the diabetic or the non diabetic participants</p>	<p>s provided by Bayer</p>
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