Trials testing intervention against other treatments

Hobbs 2007,[82] INEXACT	
Study details	
Publication type	Hobbs 2007,[82] full report in peer-reviewed journal
Additional sources of data	None
Trial design	RCT, single centre
Country	UK
Dates of participant recruitment	NR
Sources of funding	S Hobbs is supported by a British Heart Foundation Junior Research Fellowship and the Royal College of Surgeons of England 'Lea Thomas' Research Fellowship
Intervention(s) and comparator	
Treatment groups	Cilostazol 200 mg (100 mg b.i.d.). If side effects, dosing halved for 1 week, with or without exercise
Comparator	Usual care, with or without exercise
Run-in phase	No
Treatment duration	Unclear: 3 or 6 months. Follow-up 24 weeks
Outcome(s)	
Follow-up	Baseline, 12 weeks, 24 weeks
Outcomes and measures	MWD: treadmill with constant workload, 3 km/hour at a 10% incline PFWD: as MWD AEs: patient self-report
Notes on statistics	None
Population	
Eligibility criteria	IC diagnosed by Edinburgh claudication questionnaire and reduced ABPI < 0.9, reviewed after 3–6 months; MWD 20–500 m. Excluded: significant aortoiliac disease; unable to complete treadmill assessment to absolute claudication distance; MI, TIA, CVA or PTCA in past 3 months; GFR 20 ml/minute, CHF, known predisposition for bleeding
Concomitant interventions allowed or excluded	Allowed: antiplatelets, statins, antihypertensives, ACE inhibitor Disallowed: CYP3A4 or CYP2C19 inhibitors (cimetidine, diltiazem, erythromycin, ketoconazole, lansoprazole, omeprazole and human immunodeficiency virus 1 protease inhibitors)
Power calculation	32 subjects were required to detect a 50% reduction in thrombin–antithrombin complex (outcome NR in this review) in the treatment groups with 80% power and a *p*-value of < 0.05
N randomised to treatments included in review	34

ACE, angiotensin-converting enzyme; CVA, cardiovascular accident; GFR, glomerular filtration rate; NR, not reported; PTCA, percutaneous transluminal coronary angioplasty.

Treatment group	Cilostazol 100 mg b.i.d.	Usual care
N randomised to treatment	16 (nine cilostazol alone, seven cilostazol plus exercise)	18 (seven usual care alone, nine usual care plus exercise)
Baseline characteristics		
Age	Mean 58 (52 to 71) years	Mean 67 (63.5 to 74) years
Gender	M 89%	M 78%
Smokers	33%	22%
Diabetics		
Hypertension/blood pressure	(*n* = 6 on antihypertensives)	(*n* = 8 on antihypertensives)
Hyperlipidaemia		
Obesity or weight		
Angina		
History of vascular therapy		
Other		
Withdrawals		
Withdrawals/loss to follow-up	[NR by group. Of 38 participants recruited, four subjects withdrew after randomisation (three no longer wished to continue to participate in the trial, and one subject sustained a fractured ankle unrelated to trial participation)]	
Results		
MWD *n* in analysis	16	18
MWD baseline		
MWD follow-up		
MWD change	$p = 0.008$ mean ratio 1.69 (SD 0.59)	$p = 0.635$ mean ratio 1.09 (SD 0.34)
MWD between-group comparison	Cilostazol vs no cilostazol (combined groups, not just usual care group) effect 1.64, $p = 0.005$	
PFWD *n* in analysis		
PFWD baseline		
PFWD follow-up		
PFWD change		
PFWD between-group comparison		
ABPI *n* in analysis		
ABPI baseline		
ABPI follow-up		
ABPI change		
ABPI between-group comparison		
Vascular events *n* in analysis		
Vascular events follow-up		
Vascular events included		
Vascular events reported		
Vascular events between-group comparison		

Treatment group	Cilostazol 100 mg b.i.d.	Usual care
AEs *n* in analysis		
AEs follow-up		
AEs reported		
AEs between-group comparison		
Mortality reported		
Mortality between-group comparison		
HRQoL *n* in analysis		
HRQoL baseline		
HRQoL follow-up		
HRQoL change		
HRQoL between-group comparison		

M, male; NR, not reported.