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CVS-07 Earthworm extract as a fibrinolytic agent in healthy men: a randomised, double-blind, placebo-controlled study

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Introduction: "Plasmin" (Everpride Pharmaceutical) is a commercially available health food supplement that contains an earthworm extract. Preliminary studies suggested that it might have fibrinolytic properties. We therefore tested its efficacy and safety in a randomised, double-blind, placebo-controlled trial.
Method: 30 normal healthy men participated with informed consent and were randomised to either Plasmin 750 mg three times daily or matching placebo capsules for 28 days. Blood samples were taken at 1, 2, 7, 14 and 28 days for haematological and biochemical tests.
Results: There were no significance changes in blood count, renal function, liver function, blood glucose, and lipid profile. There was a small difference (1.04s ± 0.31, p=0.002) in the activated partial thromboplastin time (APTT) between Plasmin and placebo. There was no incidence of abnormal bleeding. The number of adverse events (AEs) in the 2 treatment groups (9 AEs in 4 placebo-treated subjects and 7 AEs in 3 Plasmin-treated subjects) was comparable. None of the adverse events were related to trial medication. Plasmin was well tolerated by the subjects.
Conclusions: Plasmin is a safe and well-tolerated Chinese medicine. In this short-term study, we have not found any adverse haematological effects. A large clinical trial of long duration is needed to evaluate its efficacy in the prevention of thromboembolic diseases.

CVS-08 Lipid profile of the Hong Kong Cardiovascular Risk Factor Prevalence Survey cohort

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Introduction: In 1995-6, 2881 randomly chosen Hong Kong men and women participated in the Hong Kong Cardiovascular Risk Factor Prevalence Survey. The subjects are recalled for follow up after 6 years. Here, we report the current lipid profile of the subjects who have been restudied.
Method: 813 subjects (393 men, 420 women; age 51±12 yrs) were randomly chosen from the cohort and were studied in the morning after overnight fasting. Body fat was assessed using bioelectrical impedance. Height, weight, waist and hip circumferences were measured. Blood pressure was measured carefully after resting. An oral glucose tolerance test was performed. Venous blood was taken for lipid and glucose measurement.
Results: Compared to six years ago, there were no significant changes in body weight and body mass index (BMI), but the waist circumference (WC) increased from 81.5±1.1 to 83.9±1.1 cm (p<0.001). Plasma total cholesterol increased from 5.00±0.10 mmol/L to 5.27±0.10 mmol/L (p<0.001). This was due to a rise in both HDL-C (1.2±0.03 to 1.3±0.04 mmol/L, p<0.001) and LDL-C (3.2±0.09 to 3.4±0.08, p=0.12). Plasma triglycerides were 1.6±0.06 mmol/L in men and 1.3±0.05 mmol/L in women (p<0.001). 126 (16%) and 214 (26%) subjects had diabetes and hypertension respectively. Multiple regression analysis showed that HDL-C was related (R=0.53, p<0.001) to WC (_=-0.34), sex (_=0.24), age (_=0.13), alcohol (_=-0.15), fasting glucose (_=-0.11) and diastolic pressure (_=0.09). LDL-C was related (R=0.21, p<0.001) to age (_=0.1), fasting glucose (_=0.11) and diastolic pressure (_=0.08).
Conclusions: Dyslipidaemia is associated with central obesity, high blood glucose and high blood pressure in these subjects that have been randomly selected from the general population. Our data highlight metabolic syndrome as a major problem in Hong Kong.

CVS-23 The Heart Protection Study findings with simvastatin reanalysed by number needed to treat

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Introduction: *Number Needed toTreat* (NNT) is superior to *Relative Risk Reduction* (RRR) as a means of assessing clinical trial results. We therefore opted to compare relevant RRRs and NNTs in the *MRC/BHF Heart Protection Study(HPS) with Simvastatin* the largest randomized trial of coronary heart disease (CHD) prevention to date, which recruited patients with prior CHD, diabetes or hypertension [HPS Collaborative Group 2002 Lancet 360:7-22].
Methods: Using an Excel spreadsheet to enter event rates, NNTs and respective 95% CIs were calculated and compared with corresponding published (or derived) RRRs.
Results: Respective event rates, 5 year NNTs & CIs are shown in the table.
Conclusions: NNTs are more discriminating than RRRs. They confirm that the benefits of statins: are clinically significant in terms of all-cause mortality and stroke, and that for major vascular events they are similar in persons with CHD only or diabetes only and in all cholesterol level and age categories.

Outcome of Interest		Event Rate (%)		%RRR	NNT
		Simvastatin	Placebo	(95% CIs)	(95% CIs)
All Cause Mortality		12.9	14.7	12 (5 to 18.)	57 (37 to 128)
Vascular Mortality		7.6	9.1	17 (8 to 24)	66 (44 to 134)
Non-vascular Mortality		5.3	5.6	4 (* to 15)	444 (* to 117)
1st Major CHD Event		8.7	11.8	26 (19 to 32)	32.7 (26 to 45)
1st Stroke		4.3	5.7	24 (14 to 33)	73 (50 to 131)
Revascularisaton		9.1	11.7	22 (15 to 29)	39 (29 to 58)
1st Major Vascular Event					
Total Cholesterol (mmol/L)	<5.0	17.7	23.1	23 (12 to 33)	19 (13 to 35)
	≥5.0 <6.0	16.9	24.5	23 (15 to 30)	18 (13 to 27)
	≥6.0	21.6	26.8	19 (12 to 26)	19 (14 to 30)
Age (years)	<65	16.9	22.1	23 (16 to 30)	19 (15 to 28)
	≥65 <70	20.9	27.2	23 (14 to 32)	16 (11 to 26)
	≥70	23.6	28.7	18 (9 to 26)	20 (14 to 36)
Prior CHD only		16.8	22.5	25 (17 to 33)	18 (13 to 26)
Prior Diabetes only		13.8	18.6	26 (13 to 37)	21 (14 to 40)
Prior CHD + Diabetes		33.4	37.8	11 (* to 24)	23 (12 to *)

* Denotes a negative value indicating an increased event rate in the treated group, renderng further analysis inappropriate; 1st major coronary event = non-fatal MI or CHD death; Revascularisation = coronary and non-coronary bypass and angioplasty; 1st major vascular event = 1st major coronary event, stroke or revascularisation

CVS-24 Endotoxin increases adrenomedullin expression in heart, lung and mesenteric artery

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Introduction: Previous studies have shown that the circulating levels of adrenomedullin (AM) are elevated during inflammation. The levels of AM and its messenger RNA (mRNA) in various tissues during the time course of inflammation remain to be determined.
Method: Inflammation was induced in rats by intraperitoneal injection of lipopolysaccharide (LPS, 10mg/kg). The tissues were harvested at 0, 1, 3 and 6 hours after LPS administration. Tissue levels of AM were determined by radioimmunoassay. The gene expression levels of AM were determined by solution hybridization-RNase protection assay of preproAM mRNA levels.
Results: PreproAM mRNA levels were increased in mesenteric artery and right atrium at 1 hour, in the left ventricle and the lung at 3 and 6 hours and in the right ventricle at 6 hours, after LPS injection. AM levels in the mesenteric artery were increased at 1, 3 and 6 hours and at 3 and 6 hours in the lung after LPS injection.
Conclusions: There is an increase in AM release in the lung, so it may be an important organ for AM secretion in the septic state. However, the response of the lung and the mesenteric artery to LPS in terms of AM secretion appears to be different.