

Clinical trials of plasma homocysteine lowering intervention for cardiovascular prevention in all type of patients

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1 plasma homocysteine lowering intervention

Trial	Treatments	Patients	Trials design and methods
folic acid vs control			
FOLARDA (Liem) , 2004 n=140/143 follow-up: 1 year	folic acid 5 mg per day for 1 year versus usual care	patients with acute MI and total cholesterol >6.5 mmol/l	Parallel groups open The Netherlands
GOES (Liem) , 2003 n=300/293 follow-up: 24 months	folic acid 0.5 mg per day versus usual care	patients with stable coronary artery disease	Parallel groups open The Netherlands
folic acid, B12 vs control			
NORVIT (folic acid + B12) (Bonaas) , 2006 [NCT00266487] n=1872/1877 follow-up: 36 months	folic acid 0.8mg and B12 0.4 mg daily versus no folic acid and B12	men and women who had had an acute myocardial infarction within seven days before	Factorial plan double-blind Norway
folic acid, vit B12 and vit B6 vs control			
NORVIT (folic acid, B12 and vit B6) (Bonaas) , 2006 [NCT00266487] n=937/943 follow-up: 36 months	0.8 mg of folic acid, 0.4 mg of vitamin B12, and 40 mg of vitamin B6 versus placebo	men and women who had had an acute myocardial infarction within seven days	Factorial plan double-blind Norway
vit B6 vs control			
NORVIT (vit B6) (Bonaas) , 2006 [NCT00266487] n=1871/1878 follow-up: 36 months	vit B6 40 mg daily versus no vit B6	men and women who had had an acute myocardial infarction within seven days	Factorial plan double-blind Norway
folic acid vs placebo			
CSPPT , 2015 [NCT00794885] n=10348/10354 follow-up:	enalapril 10 mg / folic acid 0.8 mg daily versus Enalapril maleate 10 mg daily	patients with primary hypertension	Parallel groups double-blind China
CHAOS-2 , 2002 n=942/940 follow-up: 1.7 y	folic acid 5 mg per day (for 2 years) versus placebo	patient with CHD	Parallel groups double blind

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Trial	Treatments	Patients	Trials design and methods
folic acid, B12 vs placebo			
WENBIT (folic ac,B12) , 2008 [NCT00354081] n=772/780 follow-up: 38.4 mo	folic acid 0.8mg, vit B12 0.4mg daily versus placebo	adult participants undergoing coronary angiography	Factorial plan double blind Norway
SEARCH , 2007 [NCT00124072] n=6033/6031 follow-up: 7 years			
	folic acid 2mg/d + vitamin B12 1mg/d versus placebo	patients survivors of myocardial infarction	Factorial plan double blind UK
folic acid, vit B12 and vit B6 vs placebo			
SU.FOL.OM3 [ISRCTN41926726] n=1242/1259 follow-up:	supplementation with natural folate, vitamin B6 and B12 versus placebo	patients with coronary or cerebral event within the previous 12 months	Parallel groups double-blind France
VITATOPS , 2010 [NCT00097669X]] n=4089/4075 follow-up: 3.4 y	folic acid and vitamins B12 and B6 in a single tablet versus placebo	patients with recent stroke or TIA (within the past seven months)
Parallel groups double-blind 20 countries			
HOPE-2 (Lonn) , 2006 [NCT00106886] n=2758/2764 follow-up: Jan 2000 - dec 2000	folic acid, 2.5 mg, vitamin B6, 50 mg and vitamin B12, 1mg versus placebo	patients 55 years of age or older who had vascular disease or diabetes and additional risk factors for atherosclerosis	Parallel groups double blind 13 countries
WAFACS , 2008 [NCT00000541] n=2721/2721 follow-up: 7.3 y	folic acid 2.5mg, vitamin B6 50mg, and vitamin B12 1mg daily versus placebo	women aged 42 years or older, with either a history of CVD or 3 or more coronary risk factors	Parallel groups double blind US
multivitamins vs placebo			
FAVORIT <i>ongoing</i> [NCT00064753] n=NA follow-up:	lowering homocysteine levels with a multivitamin versus placebo	renal transplant recipients	Parallel groups double-blind
vit B6 vs placebo			
WENBIT (vit B6) , 2008 [NCT00354081] n=772/780 follow-up: 38.4 mo	vit B6 40mg daily versus placebo	adult participants undergoing coronary angiography	Factorial plan double blind Norway
high dose - folic acid, vit B12 and vit B6 vs low dose - folic acid, vit B12 and vit B6			

continued...

Trial	Treatments	Patients	Trials design and methods
VISP (Toole) , 2004 n=1827/1853 follow-up: 2 y	high-dose of folic acid, pyridoxine (vitamin B6), and cobalamin (vitamin B12) versus low-dose of folic acid, pyridoxine (vitamin B6), and cobalamin (vitamin B12)	adults with nondisabling cerebral infarction	Parallel groups double blind United States, Canada, Scotland

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NORVIT (vit B6) (Bona), 2006:

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2 About TrialResults-center.org

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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.

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