

# Clinical trials of vit B6

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## 1 post stroke

| Trial  | Treatments  | Patients   | Trials design and methods  |
|--|---|--|--|
| <b>folic acid, vit B12 and vit B6 vs placebo</b>   |   |  |  |
| <b>VITATOPS , 2010</b><br>[NCT00097669X]   | ]n=4089/4075<br>follow-up: 3.4 y  | folic acid and vitamins B12 and B6 in a single tablet<br>versus<br>placebo | patients with recent stroke or TIA (within the past seven months)  |
| Parallel groups<br>double-blind<br>20 countries  |   |  |  |
| <b>high dose - folic acid, vit B12 and vit B6 vs low dose - folic acid, vit B12 and vit B6</b> |   |  |  |
| <b>VISP (Toole) , 2004</b><br>n=1827/1853<br>follow-up: 2 y                                    | high-dose of folic acid, pyridoxine (vitamin B6), and cobalamin (vitamin B12)<br>versus<br>low-dose of folic acid, pyridoxine (vitamin B6), and cobalamin (vitamin B12) | adults with nondisabling cerebral infarction                               | Parallel groups<br>double blind<br>United States, Canada, Scotland |

More details and results :

- prevention for post stroke in patients with prior stroke or TIA at <http://www.trialresultscenter.org/go-Q421>

## References

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Toole JF, Malinow MR, Chambless LE, Spence JD, Pettigrew LC, Howard VJ, Sides EG, Wang CH, Stampfer M Lowering homocysteine in patients with ischemic stroke to prevent recurrent stroke, myocardial infarction, and death: the Vitamin Intervention for Stroke Prevention (VISP) randomized controlled trial. JAMA 2004 Feb 4;291:565-75 [14762035]

## 2 cardiovascular prevention

| Trial   | Treatments  | Patients   | Trials design and methods   |
|---|---|--|---|
| <b>folic acid, vit B12 and vit B6 vs control</b>  |   |  |   |
| <b>NORVIT (folic acid, B12 and vit B6) (Bonaa) , 2006</b><br>[NCT00266487]<br>n=937/943<br>follow-up: 36 months | 0.8 mg of folic acid, 0.4 mg of vitamin B12, and 40 mg of vitamin B6<br>versus<br>placebo | men and women who had had an acute myocardial infarction within seven days   | Factorial plan<br>double-blind<br>Norway                          |
| <b>vit B6 vs control</b>  |   |  |   |
| <b>NORVIT (vit B6) (Bonaa) , 2006</b><br>[NCT00266487]<br>n=1871/1878<br>follow-up: 36 months                   | vit B6 40 mg daily<br>versus<br>no vit B6   | men and women who had had an acute myocardial infarction within seven days   | Factorial plan<br>double-blind<br>Norway                          |
| <b>folic acid, vit B12 and vit B6 vs placebo</b>  |   |  |   |
| <b>VITATOPS , 2010</b><br>[NCT00097669X]  | ] n=4089/4075<br>follow-up: 3.4 y   | folic acid and vitamins B12 and B6 in a single tablet<br>versus<br>placebo   | patients with recent stroke or TIA (within the past seven months) |
| Parallel groups<br>double-blind<br>20 countries   |   |  |   |
| <b>SU.FOL.OM3</b><br>[ISRCTN41926726]<br>n=1242/1259<br>follow-up:  | supplementation with natural foLate, vitamin B6 and B12<br>versus<br>placebo              | patients with coronary or cerebral event within the previous 12 months   | Parallel groups<br>double-blind<br>France                         |
| <b>HOPE-2 (Lonn) , 2006</b><br>[NCT00106886]<br>n=2758/2764<br>follow-up: Jan 2000 - dec 2000                   | folic acid, 2.5 mg, vitamin B6, 50 mg and vitamin B12, 1mg<br>versus<br>placebo           | patients 55 years of age or older who had vascular disease or diabetes and additional risk factors for atherosclerosis | Parallel groups<br>double blind<br>13 countries                   |

continued...

| <b>Trial</b>   | <b>Treatments</b>   | <b>Patients</b>   | <b>Trials design and methods</b>                                   |
|--|---|---|--|
| <b>WAFACS , 2008</b><br>[NCT00000541]<br>n=2721/2721<br>follow-up: 7.3 y                       | folic acid 2.5mg, vitamin B6 50mg, and vitamin B12 1mg daily<br>versus<br>placebo   | women aged 42 years or older, with either a history of CVD or 3 or more coronary risk factors | Parallel groups<br>double blind<br>US                              |
| <b>vit B6 vs placebo</b>   |   |   |  |
| <b>WENBIT (vit B6) , 2008</b><br>[NCT00354081]<br>n=772/780<br>follow-up: 38.4 mo              | vit B6 40mg daily<br>versus<br>placebo  | adult participants undergoing coronary angiography  | Factorial plan<br>double blind<br>Norway                           |
| <b>high dose - folic acid, vit B12 and vit B6 vs low dose - folic acid, vit B12 and vit B6</b> |   |   |  |
| <b>VISP (Toole) , 2004</b><br>n=1827/1853<br>follow-up: 2 y                                    | high-dose of folic acid, pyridoxine (vitamin B6), and cobalamin (vitamin B12)<br>versus<br>low-dose of folic acid, pyridoxine (vitamin B6), and cobalamin (vitamin B12) | adults with nondisabling cerebral infarction  | Parallel groups<br>double blind<br>United States, Canada, Scotland |

More details and results :

- plasma homocysteine lowering intervention for cardiovascular prevention in all type of patients at <http://www.trialresultscenter.org/go-Q127>

## References

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Entry terms: folic acid, Folic Acid, Vitamin M, Pteroylglutamic Acid, Folate, Folvite, Folacin,