VITATOPS INFORMATION BROCHURE

Vitamins and Stroke

Stroke remains a substantial burden on stroke patients, their carers and society. It is the third most common cause of death and the most important cause of long term physical disability in developed countries. Those who survive remain at an increased risk of having a second stroke or suffering a heart attack or blocked arteries in the legs. Therefore, one of the most important issues faced by doctors and those who have had a stroke is to prevent further strokes from happening. Unfortunately, the cause of stroke is unclear, so it is difficult to know how to prevent another stroke.

It was recently discovered that high levels of a substance called homocysteine (pronounced `home-o-sis-teen`) in the blood can damage the lining of blood vessels, causing `hardening of the arteries` (atherosclerosis). This eventually causes them to become completely blocked. When such a blockage occurs in the brain, there is poor supply of oxygen to the brain causing a stroke. However, homocysteine levels can be effectively lowered using vitamins, which means we may be able to prevent stroke by taking vitamins. As yet, no one has proven that vitamin treatment prevents stroke and other forms of blood vessel disease. The VITAmins TO Prevent Stroke (VITATOPS) Study has been designed to answer this question.

VITATOPS

VITATOPS is an international study designed to determine whether or not vitamins prevent stroke and other forms of blood vessel disease. The study is coordinated by the VITATOPS Steering Committee, which is based at Royal Perth Hospital. The study currently involves 101 centres in Australia, Austria, Belgium, Brazil, Hong Kong, India, Italy, Malaysia, Moldova, Netherlands, New Zealand, Pakistan, Philippines, Portugal, Republic of Georgia, Serbia & Monte Negro, Singapore, Sri Lanka, United Kingdom and the United States with over 6,500 patients randomised to the trial.

Patients who have recently had a stroke or TIA will be treated with either a daily multi-vitamin tablet or placebo (an ‘inactive’ tablet), for 1 to 8 years. During this time, the neurologist or physician at the VITATOPS clinic will closely monitor the patient. Neither the patient nor the doctors will know which treatment will be received. At the end of the study patients taking vitamins will be compared with those taking the placebo to determine whether vitamin treatment is beneficial or not.

Patients who join the study will be asked to take one of the prescribed tablets daily and to return to their neurologist or physician every six months to assess their progress. Patients are asked not to take any extra vitamin tablets during this study unless prescribed by their doctors (in which case we would also like to know), as this may interfere with the results of the VITATOPS Study.

Adverse-effects

All medications, including vitamins, have the potential to cause side effects. The dose of B_6 used in this study (25 mg/day) is not expected to cause any adverse effects. Much higher doses (in excess of 50 mg/day) taken over a long period of time may lead to reduced feeling in the fingers and toes (sensory neuropathy), but the effects have not been reported in lower doses as used here. While the effects of the study drug will be monitored carefully during the trial, patients who experience any side effects are encouraged to contact their neurologist or physician immediately.

Long-term Participation

Patients who decide to join the study, will be committed to take the study treatment for at least one year and up to eight years, with regular visits to the VITATOPS clinic. If patients are not willing or able to do this then we would advise them not to join the study. Those patients who join the study will be able to withdraw at any time. However, we would still like to see these patients regularly to check on their health.

VITATOPS Trial Office
Stroke Unit - Research
Royal Perth Hospital
PO Box X2213, Perth
WA, Australia, 6847

Phone: +61 8 9224 7004 or +61 8 9224 3336
Fax: +61 8 9224 8424 or +61 8 9224 3344
E-mail: VITATOPS@health.wa.gov.au