PrevANZ Vitamin D MS Prevention Trial

Quarterly Update

January 2013

Background

PrevANZ is a world-first clinical trial that will test whether vitamin D supplementation can prevent MS in those at risk of developing the disease.

The Phase IIb randomised, double blind, placebo-controlled trial will focus on the possibility of using oral vitamin D supplementation to prevent a diagnosis of MS following a person's presentation with a first episode of symptoms – **people with CIS or clinically isolated syndrome**.

PrevANZ will also test appropriate dosage levels and safety. Vitamin D3 will be administered at doses of 0 (placebo), 1000 international units (I.U), 5000 IU, and 10,000 I.U. daily for 48 weeks. Patients will be monitored by clinical and MRI measures to determine if oral vitamin D supplementation can delay or prevent a second clinical or radiological event that would result in a diagnosis of clinically definite MS.

The need for the PrevANZ trial has arisen from a now significant body of evidence for the role that vitamin D deficiency plays in MS. However, to date there has not been a clinical trial conducted to provide the necessary evidence on the benefits that can be expected from vitamin D supplementation or the correct dose.

This is an area in which the expertise in Australia and New Zealand can contribute significantly to the prevention and better treatment of MS globally.

Progress

Steering Committee

Over the second half of 2012 MSRA has been working with the PrevANZ Steering Committee to make all the necessary preparations to commence the trial.

The steering committee is chaired by Prof Bill Carroll and was established to guide the development of the trial protocol and oversee the trial throughout. The Steering Committee comprises MS neurologists, epidemiologists, an endocrinologist, statistician and radiologist.

Contract Research Organisation

A not-for-profit contract research organisation (CRO), Neuroscience Trials Australia (NTA), based at the Florey Institute, Melbourne, has also been appointed to coordinate all logistical aspects of the trial in conjunction with the Steering Committee and principal investigators.

Trial sites

20 trial sites (15 in Australia, 5 in New Zealand) have committed to conduct the trial. These sites represent the major MS clinical trial centres in Australia and New Zealand, with highly experienced MS neurologists and trialists as the principal investigators.

Central MRI reading centre

Following a tender process, the leading international MS radiology team, led by Prof David Miller at Institute of Neurology, University College London, UK, has been contracted to undertake the central reading of MRI scans. Using a central MRI reading centre ensures that all scans are analysed and reported in a consistent manner. The UK team were very keen to be involved in the study, and will collaborate closely with the PrevANZ team. Their expertise will be a great asset for the successful completion of the trial.

Vitamin D capsules

Lipa Pharmaceuticals, a contract manufacturing company, was successful in the tender process for supply of vitamin D capsules (and placebo). The product has been manufactured (Nov 2012) and will be delivered to the central pharmacy at the Austin Hospital, Melbourne in January 2013.

Logistics

The Protocol, Patient questionnaires and Patient Informed Consent Forms have been finalised. The electronic clinical research form (eCRF) for data capture and laboratory manual for investigators at the PrevANZ trial sites will be completed this week. Arrangements for the storage and data management of all biological samples associated with the trial have also been made.

Ethics approvals have been obtained from the Human Research Ethics Committees of all institutions involved in the trial and most regulatory approvals have also been obtained.

Site initiation and enrolment

With all of this in place NTA will now conduct site initiation visits with all trial investigators in the second half of January and first half of February. As soon as site initiation has taken place the investigators can commence enrolling eligible patients. Hence we anticipate that the first patients will be enrolled in late February, early March.

Funding

With contributions from Foundation 5 Million+, Trish MS Research Foundation, the John T Reid Charitable Trusts, MS Societies of WA, Tasmania and Queensland, Clayton Utz Foundation and other private donors, the trial budget stands at $2.6 million dollars. This will allow a statistically valid cohort of approximately 180 patients. Efforts continue at MSRA to raise a further $1 million to achieve a fully enrolled trial of 240 patients for a statistically robust and conclusive result to the trial.

Thank you for your support