

Vaccine trial flags challenge to celiac disease

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An effective clinical treatment for coeliac disease (or gluten intolerance) is the ultimate objective of WEHI clinician scientist, Dr Bob Anderson. This month will see the beginning of a Phase 1 clinical trial for an experimental vaccine in Melbourne. If the vaccine development and public awareness endeavours of Dr Anderson and his scientific team prove successful, a strict gluten free diet for coeliacs could become a thing of the past, while previously undiagnosed coeliacs could be detected and spared from premature deaths.

Using forty volunteers who suffer from coeliac disease, the early trial will test for drug safety - in particular, an appropriate drug dose range will be ascertained and any adverse effects will be noted. If within the course of a year the Phase 1 trial is deemed successful, a Phase 2 trial will beckon to determine the clinical effectiveness of the vaccine.

Coeliac disease is a chronic, autoimmune digestive disorder. It is characterised by the body's own immune system mistakenly attacking the lining of the small intestine. The attack is caused by the body's reaction to gluten, which is a protein found in wheat, rye, barley and oats. The immediate physiological result is that the small intestine's villi - the small, upright folds and nodules that absorb nutrients - are flattened and incapacitated by errant inflammatory action.

Globally, the disease is estimated to affect the lives of more than 6 million people in Europe, North America and Australia - but at least 5 million may be unaware that they are suffering from the disease. While people in this latter group are likely to feel the direct effects and



sometimes life-threatening complications of coeliac disease, the root cause of their debilitation nevertheless remains undiagnosed.

Long-term risks for untreated coeliac disease include malnutrition, male and female infertility, osteoporotic fractures, liver failure and cancer. Presently, the only effective treatment for coeliac disease is a life-long avoidance of any food or drink that contains the slightest trace of gluten.

Dr Anderson said, "As both a coeliac disease researcher and treating gastroenterologist, I am in an interesting position. I have overseen my basic scientific discovery about the troublesome elements in gluten being translated into an experimental vaccine that may eventually help my patients.

"There is actually a third aspect to my involvement in this project. While WEHI has provided the essential infrastructure for my scientific research, I have gone a step further and created a company, Nexpep, to lead development of the vaccine and to work closely with other Melbourne based, early stage pharmaceutical development specialists, Medicines Development Ltd and Nucleus Network.

"The vaccine itself is intended to gradually desensitize the coeliac sufferer, so that gluten is tolerated. Consequently, the villi in the small intestine should revive and absorb nutrients in the normal way. Ideally, that would mean the end of gluten-free diets for people with coeliac disease."

Source: Research Australia (<u>news</u> : <u>web</u>)

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