

World-first coeliac disease vaccine enters Phase 2 trials

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Head of coeliac research at the Institute Dr Jason Tye-Din is leading the Melbourne Phase 2 trial of immune therapy Nexvax2. Credit: Walter and Eliza Hall Institute of Medical Research

A coeliac disease vaccine that aims to protect patients from the harmful effects of gluten has entered Phase 2 clinical trials in Melbourne.

Following the commencement of global [trials](#) led by US-based pharmaceutical company ImmusanT Inc., the Australian trials will commence at the Royal Melbourne Hospital Clinical Trials Centre in Melbourne and then roll out in Perth, Adelaide, Brisbane, Mackay and the Sunshine Coast.

Led by the Walter and Eliza Hall Institute's head of coeliac research and gastroenterologist at the Royal Melbourne Hospital Dr. Jason Tye-Din, the Melbourne trial of Nexvax2 (RESET CeD) is now recruiting for patients with coeliac [disease](#).

Coeliac disease is caused by an immune reaction to the gluten protein found in wheat, rye and barley. The autoimmune disease is becoming increasingly prevalent, and is estimated to currently affect one in 70 Australians and 1.4 per

cent of the global population.

Dr. Tye-Din said volunteer participation was crucial to the success of the trials. "The vaccine is designed to target the 90 per cent of coeliac disease patients with the HLA-DQ2 genetic form of disease," he said.

Dr. Tye-Din said he was very excited about the commencement of Phase 2 trials because of the therapy's potential for one day enabling patients to safely have gluten in their diet. "A successful therapy that can restore normal gluten tolerance would revolutionise coeliac disease management.

Nexvax2 is designed to restore what is lost in coeliac disease – the ability of the immune system to tolerate gluten.

President of Coeliac Australia Mr Michael Bell said the organisation's members and many thousands of Australians with coeliac disease had been looking forward to the announcement of Phase 2 trials.

"Many have been following the development of Nexvax2 for more than a decade and are hopeful the trials will take us one step closer to an effective treatment for coeliac disease," Mr Bell said.

Building on Institute research

Dr. Tye-Din has been leading the way in understanding what triggers coeliac disease in a combined effort involving patients, clinicians and scientists for more than a decade.

Initiated by Dr. Bob Anderson, now chief scientific officer for ImmusanT Inc., and Dr. Tye-Din in 2003, the Institute's coeliac research program identified the toxic parts – or peptides – of gluten that led to the design of the targeted immune treatment and subsequent Phase I trials undertaken in Melbourne.

"The results from national and international Phase

1 trials showed that the therapy was safe and well tolerated even at the highest doses used, and also showed an intended biological effect on the immune system in patients with coeliac disease. The Phase 2 trials build on the data from earlier studies and it is great that Australia is still playing a pivotal role in this work," Dr. Tye-Din said.

Patients who are interested in partaking in the Melbourne-based Phase 2 trial of Nexvax2 (RESET CeD) for the treatment of [coeliac disease](#) are invited to visit the Royal Melbourne Hospital website or contact the Walter and Eliza Hall Institute's coeliac team at coeliac@wehi.edu.au.

For a list of sites offering the trial in Australia please visit the [Coeliac Australia](#) website.

Provided by Walter and Eliza Hall Institute of Medical Research

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