

Testing whether vitamin D delays onset of diabetes

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Northwestern Medicine is looking for volunteers to take part in the first definitive, large-scale clinical trial to investigate if a <u>vitamin D</u> supplement helps to delay or prevent the onset of type 2 <u>diabetes</u> in adults who have prediabetes and are at high risk for type 2. Funded by the National Institutes of Health (NIH), the study is taking place at about 20 study sites across the United States.

The Vitamin D and Type 2 Diabetes (D2d) study will include about 2,500 people. Its goal is to learn if vitamin D—specifically D3 (cholecalciferol)—will delay the onset of type 2 <u>diabetes</u> in adults age 30 or older with prediabetes. People with prediabetes have <u>blood glucose</u> levels that are higher than normal but not high enough to be called diabetes.

D2d is the first study to directly examine whether a daily dose of 4,000 International Units (IUs) of vitamin D—greater than a typical adult intake of 600-800 IUs a day but within limits deemed appropriate for clinical research by the Institute of Medicine—helps keep people with prediabetes from getting type 2 diabetes. Based on observations from earlier studies, researchers speculate that vitamin D could delay the onset of diabetes in 25 percent of prediabetic subjects. The study will also examine if sex, age or race affect the potential of vitamin D to reduce diabetes risk.

"Millions of Americans are at risk for diabetes, a serious condition that can lead to heart disease, kidney disease and blindness," said Lisa Neff,



M.D., assistant professor of medicine at Northwestern University Feinberg School of Medicine and an endocrinologist at Northwestern Memorial Hospital. "Evidence from preliminary studies suggests there may be a link between vitamin D and diabetes risk. The D2d trial will help us determine whether vitamin D can delay the onset of diabetes in people at risk for the disease."

Half of the study participants will receive vitamin D. The other half will receive a placebo. Participants will have check-ups for the study twice a year.

The study will be double-blinded, so neither participants nor the study's clinical staff will know who is receiving vitamin D and who is receiving the placebo. The study will continue until enough people have developed type 2 diabetes to be able to make a scientifically valid comparison between diabetes development in the two groups, likely about four years.

D2d builds on previous NIH-funded studies of methods to delay or prevent type 2 diabetes, including the Diabetes Prevention Program, which showed that, separately, lifestyle changes to lose a modest amount of weight and the drug metformin are both effective in slowing development of type 2 diabetes in people with prediabetes. However, additional safe and effective preventative strategies are needed to stem the increasing numbers of people developing type 2 diabetes.

Provided by Northwestern University

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