

D2d Collaborating Clinical Sites

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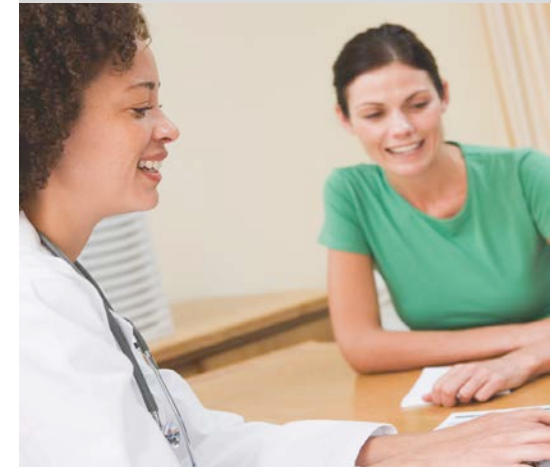
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Vitamin D and type 2 diabetes



Are You at Risk for Type 2 Diabetes?

You may qualify for a research study

The study is sponsored by



www.d2dstudy.org



Diabetes means that the glucose (sugar) level in the blood is too high. Cells in the body use glucose for energy and the hormone insulin is needed to bring the glucose from the blood into the cells. In type 2 diabetes, blood glucose is too high because the body does not produce enough insulin or the cells ignore the insulin that is produced. People with high blood glucose levels have an increased risk for many serious complications, including heart disease, blindness, nerve damage and kidney damage. According to the Centers for Disease Control and Prevention, about 2 million adults are diagnosed with diabetes in the United States every year.

Vitamin D is a hormone with many actions throughout the body. Humans make vitamin D in the skin upon exposure to sunlight. Vitamin D is also found naturally in some foods (salmon, eggs), but in very small amounts. Because of limited exposure to natural sunlight and suboptimal diet, many people have lower vitamin D levels than in the past. Preliminary studies have suggested that a low vitamin D level in the blood may be associated with development of many chronic diseases, including diabetes. However, whether supplementation with vitamin D is beneficial for diabetes and other medical conditions is not known.



Vitamin D and
type 2 diabetes

What is the D2d Study About?

Physicians at 20 sites across the United States are conducting a research study in adults at risk for diabetes to see whether daily vitamin D supplementation can delay the onset of diabetes. Understanding whether vitamin D has an effect on glucose (sugar) metabolism may lead to new treatments for diabetes.

According to the Centers for Disease Control and Prevention, about 80 million people are at risk for developing diabetes. Persons who are older than 45 years of age, are overweight, have a family member with diabetes, have high blood pressure, or who do not get enough exercise are at risk for type 2 diabetes. Women who had diabetes during pregnancy and people from certain ethnicities are also at risk.

What Can You Do?

If you think you may be at risk for diabetes and would like to get more information about the study, please call a clinical site (see opposite page), or visit us on-line at:

www.d2dstudy.org



Who Qualifies for the Study?

Men and women older than 30 years who are at risk for diabetes.

You must agree not to take nutritional supplements or other preparations during the study containing vitamin D in excess of 1000 units per day or calcium in excess of 600 mg per day from all sources combined.

Persons with diagnosed diabetes, kidney stones or kidney disease are not eligible. Other exclusions also apply.

If you are interested in participating, you will have a brief interview over the telephone and, if eligible, a screening visit at one of the sites shown on the opposite page.

What is Involved?

If you qualify, you will be assigned randomly (by chance) to receive a study pill containing either vitamin D or placebo (a substance with no known effects). Participants will be required to take one pill every day for the duration of the study and will need to come to the medical clinic for the study visits.

Participants will be compensated for time and travel related to the study visits

Study Visits

After the Screening visit, qualified participants will come to the clinic for 4 study visits during the first 6 months and then once every 6 months for approximately 4 years. Additional visits may be required. Visits will be scheduled in the mornings. Participants will be required to fast (no food or drink except water) overnight for 8 hours before each visit.

Study visits will include the following:

- Answering questions about your health, diet, and physical activity.
- Measurement of height, weight, and blood pressure.
- Blood draw and collection of urine.
- At the beginning of the study and every year (or more often if needed), an Oral Glucose Tolerance Test.

Potential Benefits

During the Screening visit, participants will have access to the results of the medical examination, including results of certain blood tests, which they can share with their doctors. During the study, participants will be followed by development of diabetes. At the end of the study, participants will be provided with a copy of the overall study results.