

Improving Recovery with Vitamin D: Learn About the VITdALIZE-KIDS Trial for Children

By

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The Importance of Vitamin D:

This article is intended as a patient education resource to help you understand the role of vitamin D and why researchers are studying it in children recovering from serious illness.

Vitamin D is an important vitamin needed by all people for survival. It promotes the growth of healthy bone and muscle, prevents heart disease, decreases inflammation, and supports healthy blood vessels.

Vitamin D is made by the body when we are in the sun. It can also be found in some foods and supplements. Many people in Canada and throughout the world are not getting enough.

Vitamin D Deficiency (VDD) is a condition where the level of Vitamin D found in the blood is less than 50 nmol/L (a standard measure used in blood tests). It has been linked with increased illness, multiple organ dysfunction, and higher rate of death. This deficiency can make other illnesses worse, especially in people already facing serious health problems.

Purpose of the Study:

The aim of this clinical trial is to determine whether a rapid increase of vitamin D, in children recovering from critical illness, will improve their quality of life.

Why Participate in this Study?

Participation in the study is voluntary. It is your choice whether your child takes part in this clinical study. You do not have to take part in this study in order to receive treatment or care.

Rapid treatment of VDD can help strengthen the immune system, ease swelling and irritation, and improve overall health. It may lead to better recovery and fewer complications from other treatments.

We do not know if you will receive medical benefit from participation, but researchers hope that this study will fulfil its purpose and benefit others in future.

Risks of Study Participation:

Vitamin D is generally safe, and serious side effects are rare. In this study, children will receive a single dose of 10,000 IU of vitamin D per kilogram of body weight, up to a maximum of 400,000 IU..

Even though side effects are rare, they may still happen. Some people may get high calcium levels in their blood. This can cause nausea, constipation, or muscle weakness. These side effects usually happen with very high doses.

It is important to note that VITdALIZE-KIDS is a phase III clinical trial, meaning that dosage and safety have been previously established in a pilot study.

Although Vitamin D is generally safe and shows promise, it is not yet proven that rapid treatment will benefit all children in the same way. That is why this research is being done; to learn more and improve care for the future.

Please talk to your usual doctor or the study doctor about the known benefits and risks of these other options before you decide to take part in this study.

Informed Consent:

It is very important that informed consent is respected, and that you and your child understand the study before agreeing to take part. Informed consent helps make sure that you and your child understand the trial's purpose and what to expect before deciding to participate. You will be provided with information about what the study is for, how it works, and any possible risks or benefits.

Informed consent is ongoing throughout the trial, and participants may choose to withdraw consent/assent at any time.

Study Procedures:

This is a randomized, double-blind controlled clinical study, which means that 50% of trial participants will receive the actual treatment (vitamin D), and the other 50% will receive a placebo. The placebo is identical in administration and appearance to the actual treatment, but with no active ingredients. During the clinical study, neither clinicians, staff, nor caregivers or patients will know which group they belong to.. You will not get to choose what group you will be in.

Approximately 766 children are expected to take part in this study across multiple sites. Your child will be eligible to participate in this study if they have critical illness status – such as multiple organ dysfunction – and admission to the Pediatric Intensive Care Unit (PICU) with confirmed VDD.

Your child may not qualify to participate in this study if they have any condition which makes high dosage of Vitamin D dangerous to them, or if they have participated in similar studies in the past. It is also important that you consult your doctor when making a decision, as there may be certain treatments that your doctor is providing that may interfere with the study results and outcomes.

Children will receive the treatment shortly after they enrol in the study. During the study, their Vitamin D levels, organ function, and overall health will be monitored weekly over a period of 28 days after which a follow-up will be done within 90 days.

During the course of the study, your child will go through scheduled assessments to check Vitamin D levels and health status. The assessments used in this study are standard Vitamin D blood tests, blood samples, urine samples, and quality of life questionnaires.

The following assessment timeline should be completed:

- **Before joining the study:** Eligibility screening, blood test, informed consent
- **Day 0:** Study drug or placebo
- **Follow-ups:** Check-ins at 72 hours, 28 days, and 90 days

To help make the study successful and support your child's health, it is important to attend all appointments, especially if your child is not staying in the hospital. If you miss any follow-up assessments, we will send you reminders to help you stay on track.

As a thank-you for completing the study, you will receive a \$25 gift card.

Next Steps?

If you are interested in learning more or enrolling your child in the VITdALIZE-KIDS study, please speak to your doctor or with a member of the clinical team. They will be happy to answer your questions, explain the process in more detail, and help you decide whether this study is a good fit for your child.

You do not have to decide right away. Take your time to read the information provided, ask questions, and discuss your options with your family and your child's healthcare provider. If you choose to participate, the team will guide you through the informed consent process and support you at each stage of the study.

A more detailed description of the clinical study is available at [Rapid normalization of vitamin D deficiency in PICU \(VITdALIZE-KIDS\): study protocol for a phase III, multicenter randomized controlled trial | Trials | Full Text](#).