

PROTOCOL: INTERVENTION STUDY (CLINICAL TRIALS)

Title: Impact of Vitamin D Therapy on Thyroid Function and Antibody Levels in Pediatric Graves' Disease: A Pilot Feasibility Trial

Protocol Number: 25-0285

Principal Investigator:

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Title Pediatric Endocrinologist

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Investigational Product Name(s): ergocalciferol

IND or IDE Number (*if applicable*): NA

Regulatory Sponsor (*Sponsor-Investigator or IND/IDE holder, if applicable*): NA

Name

Address

Phone number

Email address

Protocol Version and Date: version 1. 6.26.2025

Northwell Health

Campus: Cohen Children's Medical Center

Assent to be in a Research Study

Title: Impact of Vitamin D therapy on thyroid function and antibody levels in Pediatric Graves' disease – A Pilot Feasibility Study

1. My name is Dr. Sharon Hyman
2. We are asking you to take part in a research study because we are trying to learn more about how vitamin D treatment impacts children with overactive thyroid glands and their levels over time.
3. If you decide to be in this study, you will not require any additional blood work drawn than you are already getting. We will be getting an additional blood test for a vitamin D level at the time of your initial lab tests, and again at 3 months and 6 months when you would normally be getting labs anyway.
4. If you decide to be in this study, there is a chance you may end up having to take an extra pill that contains vitamin D – initially every week for 8 weeks and then every 2 weeks for 4 months.
5. Sometimes things that don't feel good happen in research studies. You might feel a pinch when we draw your blood and may get a bruise or feel sore, but we will be taking a small amount of blood as part of your regular evaluation.
6. People may also have good things happen to them when they are in research studies. The good things may be that you could help us learn more about whether vitamin D can help children that have overactive thyroid glands get better earlier than children that do not get additional vitamin D. You will be helping the doctors learn more about whether getting the vitamin D levels to normal will help other children with overactive thyroids get better faster.
7. Please talk to your parents about this before you decide whether to be in this research study. We will also ask your parents to give their permission for you to be in this study. But even if your parents say "yes," you can still decide not to be in this research study.
8. If you do not want to be in this study, you do not have to.
9. You may stop being in this study at any time. Remember, being in this study is up to you and no one will be upset if you don't want to take part in this study or even if you change your mind later and want to stop.

10. You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call me at 516-472-3750 or ask me next time.

11. Putting your name at the bottom means that you have decided to be in this study. You and your parents will be given a copy of this form after you have signed it.

Name of Subject

Sign your name here ↑

Date

Witness' Printed Name

Witness' Signature

Date

Investigator's Printed Name

Investigator's Signature

Date