

Correlation Vitamin D Level to Endocrine Autoimmune Toxicity Due to Immune Checkpoint Inhibitors

NCT04615988

Status	RECRUITING
Sponsor	Icahn School of Medicine at Mount Sinai
Enrollment	17 participants

Plain Language Summary

This study is investigating whether vitamin D levels affect the risk of developing hormone-related side effects (like thyroid problems) in cancer patients receiving immune checkpoint inhibitor drugs (a type of immunotherapy). It does not test a new treatment — it observes patients during their standard immunotherapy.

****You may be eligible if...****

- You have a cancer being treated with PD-1 or PD-L1 immune checkpoint inhibitor drugs
- You are 18 or older
- You are willing to complete symptom questionnaires and allow regular blood draws

****You may NOT be eligible if...****

- You already have a known thyroid condition (overactive or underactive thyroid)
- Your hemoglobin is very low (below 9)
- You are actively supplementing with vitamin D for a deficiency (routine multivitamins are okay)
- You are pregnant or breastfeeding
- You have a history of pituitary inflammation (hypophysitis)
- You cannot attend all required study visits

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (5)

- Malignancy which the treating oncologist plans for next treatment to inhibit PD-1 or PD-L1 with the immune inhibitor being the only immunotherapy. Twenty-five subjects in a separate cohort will need for eligibility to be planned for treatment with anti-PD1/PD-L1 plus antr-CTLA-4 therapy.
- Willingness to complete symptom questionnaires
- Willingness to allow blood draws
- Ability to provide informed consent
- Age > 18 years old

Exclusion (6)

- History of clinical or subclinical hyperthyroidism or hypothyroidism
- Hemoglobin < 9
- Inability to come for all study visits.
- Actively on vitamin D supplementation due to vitamin D deficiency (As part of a multivitamin is not exclusionary)
- Pregnant or lactating
- ... and 1 more (see full listing online)

Locations (1 total)

<https://clinicaltrials.gov/study/NCT04615988>

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