

# Study of CAR T-Cells Targeting the GD2 With IL-15+iCaspase9 for Relapsed/Refractory Neuroblastoma or Relapsed/Refractory Osteosarcoma

NCT03721068

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 1
<b>Sponsor</b>	UNC Lineberger Comprehensive Cancer Center
<b>Enrollment</b>	18 participants

## Plain Language Summary

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This trial is testing a new cell therapy called iC9.GD2.CAR.IL-15 — where a patient's own immune T cells are genetically engineered to target a protein called GD2 found on neuroblastoma (a childhood cancer) and osteosarcoma (a bone cancer) cells — in children and young adults whose cancer has relapsed or stopped responding to other treatments.

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

- You have been diagnosed with high-risk neuroblastoma or osteosarcoma that has relapsed or not responded to standard treatment
- Your cancer was originally confirmed by tissue biopsy or bone marrow sample
- You are in acceptable overall health (Lansky or Karnofsky score of 60 or above)
- Your life expectancy is at least 12 weeks
- Your guardians have signed consent (HIPAA authorization)

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

- Your cancer does not express the GD2 protein at adequate levels
- Your blood counts or organ function do not meet minimum requirements
- You have active, uncontrolled brain tumors or spinal fluid involvement
- You are pregnant or breastfeeding
- You have had a prior allogeneic (donor) stem cell transplant or another CAR T-cell therapy

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

## Key Eligibility Criteria

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### Inclusion (14)

- All clinical and laboratory data required for determining eligibility must be available in the subject's medical/research record which will serve as the source document.
- Because of the nature of iC9.GD2.CAR.IL-15 T cell product preparation, subjects will be assessed for initial study enrollment eligibility (prior to cell procurement) and then will have to meet criteria prior to starting lymphodepletion and prior to T cell infusion.
- Written HIPAA authorization signed by legal guardian.
- Adequate performance status as defined by Lansky or Karnofsky performance status of e 60 (Lansky for <16 years of age).
- Life expectancy e12 weeks.
- ... and 9 more (see full listing online)

### Exclusion (4)

- Pregnant or breastfeeding (NOTE: breast milk cannot be stored for future use while the mother is being treated on study).
- Has a known additional malignancy that is active and/or progressive requiring treatment.
- History of hypersensitivity reactions to murine protein-containing products.

<https://clinicaltrials.gov/study/NCT03721068>  
DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).

- History of hypersensitivity to cyclophosphamide or fludarabine.

## Locations (2 total)

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Emory - Winship Cancer Institute, Atlanta, Georgia, United States

Lineberger Comprehensive Cancer Center at University of North Carolina - Chapel Hill, Chapel Hill, North Carolina, United States