

# Leveraging Chimeric Antigen Receptor-Expressing T Cells for Children with Diffuse Midline Glioma

ACTRN12622000675729

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Status	RECRUITING
Sponsor	Sydney Children's Hospitals Network
Enrollment	18 participants

## Plain Language Summary

Diffuse midline glioma, including diffuse intrinsic pontine glioma (DIPG), is one of the most devastating brain tumours in children. It grows in the brainstem or other deep parts of the brain that control breathing and movement, making surgery impossible. Standard radiotherapy can temporarily slow the tumour but rarely controls it long-term, and there are very few effective treatments. This study tests a cutting-edge approach called CAR T-cell therapy — using the patient's own immune cells, specifically engineered in the laboratory to recognise and attack the tumour.

The patient's T cells are collected, genetically modified to target a protein called GD2 that is found on the surface of these tumours, and then infused back into the body. The study tests different doses to find the safest and most effective level, and also evaluates giving the therapy directly into the brain's fluid spaces. Participants are monitored closely for toxicity and tumour response.

You may be eligible if your child is 21 years of age or younger, has a confirmed diagnosis of DIPG by MRI or a diffuse midline glioma with specific genetic markers, has adequate bone marrow and organ function, and has a life expectancy of at least 12 weeks. Children who have already experienced tumour progression after radiation or who have active autoimmune disease are not eligible for the treatment phase.

## Key Eligibility Criteria

### Inclusion (16)

- Written informed consent;
- Age less than or equal to 21 years old at the time of study enrolment;
- Diffuse Intrinsic Pontine Glioma (DIPG) diagnosed by MRI and/or histological diagnosis of Diffuse Midline Glioma (DMG) with an H3K27M mutation or loss of H3K27 trimethylation;
- Lansky / Karnofsky score greater than or equal to 50%;
- Absolute lymphocyte count greater than or equal to  $0.1 \times 10^9/L$ ;
- ... and 11 more (see full listing online)

### Exclusion (26)

- Inadequate bone marrow reserve as demonstrated by an absolute neutrophil count less than or equal to  $1.0 \times 10^9/L$  or platelet count less than or equal to  $100 \times 10^9/L$  (cannot be post-transfusion) or haemoglobin less than 105 g/L (can be post-transfusion);
- Patient weight less than 5kg;
- Patient is not medically fit for apheresis procedure;
- Participation in a trial of an investigational agent within the 7 days prior to enrolment;
- Pregnant or breast-feeding females;
- ... and 21 more (see full listing online)

## Locations (1 total)

Sydney Children's Hospital - Randwick, NSW, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12622000675729>

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