

# Treosulfan Therapeutic Drug Monitoring in Pediatric Hematopoietic Stem Cell Transplant Recipients

NCT06861257

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Status	RECRUITING
Sponsor	Fondazione IRCCS Policlinico San Matteo di Pavia
Enrollment	70 participants

## Key Eligibility Criteria

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### Inclusion (7)

- Age range 0 - 18 years.
  - Life expectancy  $\geq$  12 weeks.
  - Diagnosis of malignant or non-malignant disorder.
  - Pre-HSCT Lansky / Karnofsky score  $\geq$  40%.
  - Indication to allogeneic or autologous HSCT with TREO as part of the pre-transplant conditioning regimen.
- ... and 2 more (see full listing online)

### Exclusion (7)

- Absence of written informed consent signed by the parents or guardians.
  - Current clinically active infectious disease (including positive HIV serology or viral RNA).
  - Severe cardiovascular disease (arrhythmias requiring chronic treatment, congestive heart failure or left ventricular ejection fraction  $<$ 40%).
  - Liver dysfunction (AST/ALT  $\geq$  3 times institutional upper limit normal value -ULN- or bilirubin  $\geq$  3 times ULN).
  - Renal dysfunction: serum creatinine  $\geq$  1.5 times ULN or calculated creatinine clearance  $<$  60 ml/min/1.73 m<sup>2</sup>
- ... and 2 more (see full listing online)

## Locations (10 total)

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Policlinico Sant'Orsola Malpighi, Clinica Pediatrica Oncologia Ed Ematologia Pediatrica "Lalla Seràgnoli", Bologna, bOLOGNA, Italy  
Ospedali Civili, Presidio Ospedale Dei Bambini, Oncoematologia Pediatrica e TMO, Brescia, Brescia, Italy  
IRCCS Istituto Giannina Gaslini, U.O.S.D. Centro Trapianto di Midollo Osseo, Genova, Genova, Italy  
... and 7 more locations