

# Pilot Trial of Allogeneic Blood or Marrow Transplantation for Primary Immunodeficiencies

NCT02579967

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Status	RECRUITING
Phase	Phase 2
Sponsor	National Cancer Institute (NCI)
Enrollment	354 participants

## Key Eligibility Criteria

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### Inclusion (32)

- Patients age  $\geq$  4 through 75 years
- PID deemed to be of sufficient past severity to warrant allo BMT, by meeting the two criteria below:
- PID as defined by identified genetic defect or, in the absence of a PID-associated genetic mutation, patients with an immune defect potentially amenable to allo BMT who meet the clinical history criteria below may be eligible upon discussion with the PI
- Mutations should be confirmed in a CLIA-certified laboratory, if such testing is available.
- Patients without a mutation must be deemed eligible and appropriate for allo BMT by the PI. Some patients may meet the clinical history criteria listed below, but will not be eligible if it is thought that their clinical history is due to a condition apart from an immune defect. In addition, patients with a PID of mild severity, such as those with selective IgA deficiency, may meet at least two of the clinical history criteria, but may be deemed inappropriate for allo BMT by the PI if it is felt that the risks of the procedure outweigh the severity of the disease.

... and 27 more (see full listing online)

### Exclusion (9)

- Patients who are receiving any other investigational agents, with the exception of virus-specific cytotoxic T-cells for the treatment of viral infection/reactivation prior to allo BMT.
- History of allergic reactions attributed to compounds of similar chemical or biologic composition to agents (cyclophosphamide, busulfan, pentostatin, sirolimus, MMF, filgrastim or filgrastim biosimilar) used in the study
- Active psychiatric disorder which may compromise compliance with the transplant protocol, or which does not allow for appropriate informed consent
- Active central nervous system (CNS) involvement by malignancy, except in cases of virus-associated malignancies with CNS involvement in which case the patient may benefit from the transplant to control the malignancy.
- MAGT1 mutation and active need to take anti-platelet agents and/or therapeutic anti-coagulation that cannot be interrupted during aplasia.

... and 4 more (see full listing online)

## Locations (2 total)

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National Institutes of Health Clinical Center, Bethesda, Maryland, United States  
National Marrow Donor Program, Minneapolis, Minnesota, United States

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<https://clinicaltrials.gov/study/NCT02579967>

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