

Improving White Blood Cell Collection From Healthy Donors

NCT01553214

Status	RECRUITING
Phase	Phase 4
Sponsor	National Institutes of Health Clinical Center (CC)
Enrollment	1,000 participants

Key Eligibility Criteria

Inclusion (5)

- Donors shall meet all donor eligibility criteria for allogeneic blood donors, as defined in the most recent editions of the AABB Standards and FDA Code of Federal Regulations (21CFR640). In addition, donors shall meet the following restrictions:
- Age greater than or equal to 18 and less than or equal to 75 years
- If hypertension is present, must be well-controlled on medications
- If peptic ulcer disease has been diagnosed in the past, symptoms must be well-controlled on medications
- If cataracts have been diagnosed in the past, records from subject's ophthalmologist must be obtained indicating type of cataract. If PSC was diagnosed in the past, subject may receive G-CSF but not dexamethasone. The only exception to this is a history of bilateral cataract extractions due to PSC.

Exclusion (11)

- Information obtained from health history screen that does not meet the allogeneic donor eligibility criteria of the AABB Standards or the FDA CFR.
- Weight less than 50 kg (110 lbs).
- History of coronary heart disease
- Uncontrolled hypertension (systolic BP \geq 160, diastolic BP \geq 100)
- Diabetes mellitus requiring insulin
- ... and 6 more (see full listing online)

Locations (1 total)

National Institutes of Health Clinical Center, Bethesda, Maryland, United States