Will you receive study medication in this trial?
Yes. The study will consist of 12-month treatment and 12-month follow-up, of monthly transfusions with G-CSF Mobilized Fresh Frozen Plasma (GMFFP) harvested from young, healthy donors.

How is the study medication given?
The GMFFP is administered intravenously (into a vein) over 1-2 hours, once monthly, for 12 months.

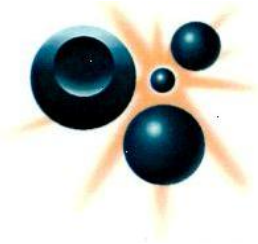
What is the study duration?
The study has an initial evaluation followed by once monthly infusions of GMFFP for 12 months and then follow ups every 3 months for 12 months for a total study period of 24 months.

How many study visits are there during the study?
This study includes 17 visits. Each visit for the first 12 months will require 3 days at the study facility and each subsequent visit during the follow up period will require 1 day at the study facility.

To find more information on the clinical trial, please call:

561-752-5522

The South Florida Bone Marrow Stem Cell Transplant Institute
10301 Hagen Ranch Road, Suite 600
Boynton Beach, FL 33437
561-752-5522



Clinical Study Evaluating the Safety and Efficacy of Fresh Frozen Plasma (GMFFP) from young healthy donors ages 18 to 35, who have received Granulocyte-Colony Stimulating Factor (G-CSF) to Enhance the Immune Risk Profile in Older Individuals and Ameliorate Frailty.

What is the Clinical Trial?

This trial is attempting to investigate if Granulocyte -Colony Stimulating Factor (G-CSF) pre-treated donors Fresh Frozen Plasma (GMFFP) is a viable option for correcting the immune dysfunction seen with frailty and unhealthy aging.

How does GMFFP affect frailty?

Given that frailty and the progression of age-associated illnesses are largely attributable to immune dysregulation, enhancing proper immune function through exposure to transfusions of GMFFP from young, healthy donors may provide a viable option for the promotion of healthy aging.

What is the purpose of the clinical trial?

This study has a primary objective of determining and demonstrating the safety and tolerability of GMFFP in older, frail individuals, and a secondary objective of determining and demonstrating the efficacy of the treatment of these individuals with GMFFP.

What is the timeline of visit requirements?

	Informed Consent	Full Medical History	Intermediate History	Update Concomitant Medications	GMFFP Transfusion	Serum Chemistry and CBC	Misc. Testing *	Monitor Adverse Events	Immune Panel **	Serum Biomarkers **	Clinical Assessments ***
Screening	X	X				X	X				% (physical exam only)
Baseline			X	X		X	X (HCG only)		X	X	X
Month 1			X	X	X	X		X			X
Month 2			X	X	X	X		X			X
Month 3			X	X	X	X		X	X	X	X
Month 4			X	X	X	X		X			X
Month 5			X	X	X	X		X			X
Month 6			X	X	X	X		X	X	X	X
Month 7			X	X	X	X		X			X
Month 8			X	X	X	X		X			X
Month 9			X	X	X	X		X	X	X	X
Month 10			X	X	X	X		X			X
Month 11			X	X	X	X		X			X
Month 12			X	X	X	X		X	X	X	X
Month 15			X	X		X		X	X	X	X
Month 18			X	X		X		X	X	X	X
Month 21			X	X		X		X	X	X	X
Month 24			X	X		X		X	X	X	X