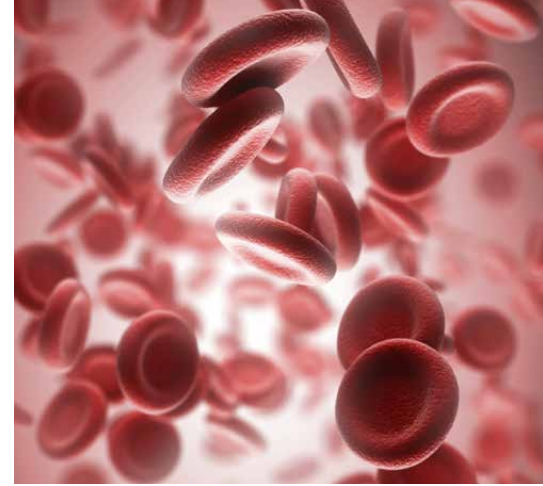




**NORTHSIDE HOSPITAL
CANCER INSTITUTE**

**BLOOD & MARROW
TRANSPLANT PROGRAM**

**The Blood & Marrow
Transplant Group**
O F G E O R G I A



Novel Multiple Myeloma Immunotherapy BMT Clinical Research Trial

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Clinical Trial Opening

Open to Enrollment: NSH-1148 A Randomized Phase II Study of Autologous Stem Cell Transplantation with Tadalafil and Lenalidomide Maintenance with or without Activated Marrow Infiltrating Lymphocytes (MILS) in High Risk Myeloma

In collaboration with Johns Hopkins BMT Program, the NSH-BMT Program is enrolling newly diagnosed or relapsed myeloma patients who have not undergone a prior transplant to this cutting-edge immunotherapy clinical research trial. Marrow infiltrating lymphocytes (MILs) can be activated, has a memory phenotype that increases the likelihood of persisting over time, and possess unique surface cell markers that increase their likelihood of trafficking to the bone marrow upon infusion. This study is aiming to show that using the patient's own activated MILs in combination with autologous stem cell transplant (ASCT) is more effective at improving long-term disease-free survival.

This is a phase II multicenter study. Patients will be randomized 2:1 to MILs vs. no MILs. All patients will undergo ASCT, will receive Tadalafil and Lenalidomide will be given as post-transplant maintenance therapy at approximately day 60 until disease progression. Patients randomized to the non-MILs arm of the trial will be able to receive MILs upon relapse.

ELIGIBILITY CRITERIA

Inclusion:

- 18-80 years of age
- Active myeloma requiring systemic treatment
- Newly diagnosed or relapsed myeloma with no previous transplant
- High-risk disease:
 1. High-risk chromosomal translocations by FISH:
t(4;14), t(14;16), t(14;20), del(17p), 1p del, 1q amplification
 2. MyPRS GEP-70 high risk signature
 3. LDH at baseline >300U/L
 4. Relapse within 12 months from prior therapy
- ECOG 0-2
- Must have had > than PR after last therapy

Exclusion:

- POEMS syndrome, non-secretory myeloma, or amyloidosis
- Previous stem cell transplant
- Use of corticosteroids within 21 days of bone marrow collection
- Use of any myeloma-specific therapy within 21 days of bone marrow collection
- Contraindication to phosphodiesterase-5 inhibitors

If you should have any questions, would like to discuss study logistics, or the eligibility of any patents, please contact Stacey Brown, NSH-BMT/Leukemia clinical research manager, at 404-851-8238 or stacey.brown@northside.com.



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