

Randomized Study: Standard of Care With or Without Atorvastatin for Prevention of GVHD for Matched Unrelated Donor BMT

ClinTrials.gov Identifier: NCT03066466

PLAIN LANGUAGE SUMMARY

AUDIENCE

This plain language summary is intended for adults who may be eligible for the clinical trial and have limited to no understanding of basic biology.

The author has no affiliation with the study cited; this sample is for illustration purposes and does not constitute medical advice.

ABOUT US

Takmos LLC is a nonclinical toxicology consulting firm based in Ventura, California serving a range of industries.

We specialize in providing plain language summaries of technical materials.

CONTACT

Takmos LLC

web: www.takmos.com

email: info@takmos.com

telephone: 805-328-3290

What is this clinical trial about?

This study will determine if the drug atorvastatin will reduce the risk of complications, specifically Chronic Graft Versus Host Disease, following bone marrow transplants. It is a study for patients receiving a bone marrow stem cell transplant from a matched donor that is not a family member.

What is Chronic Graft Versus Host Disease?

Chronic **Graft Versus Host Disease** also called **GvHD** is an immune response to your transplant than occur at any time after the transplant, even several years later. The immune reaction may cause effects in the the skin, liver, eyes, mouth, lungs, neuromuscular system, genitourinary tract, or gastrointestinal system.

GVHD and is more common when the donor is not a family member of the the patient receiving the transplant.

Methotrexate and tacrolimus are given after bone marrow transplant to reduce the risk of GvHD.

What is the goal of this trial?

To prevent GVHD, bone marrow transplant patients are typically given a combination of two drugs called methotrexate and tacrolimus. These drugs suppress the immune system and this treatment is called the "standard of care". The goal of the study is to determine whether the risk of GVHD can be reduced by the addition of atorvastatin to the standard of care. This study is specific to patients receiving a bone marrow stem cell transplant from a matched donor that is not related.

Turn the page to learn more.



PLAIN LANGUAGE SUMMARY CONTINUED

What is atorvastatin?

Atorvastatin is a medication taken by mouth that is commonly prescribed for the control of cholesterol. This drug may reduce the risk of GVHD when given in combination with methotrexate and and tacrolimus.

If you are enrolled in this study, you may be given atorvastatin in addition to the usual treatment of methotrexate and tacrolimus.

Who can join this trial?

You may be enrolled in this study if you are over 18 less than 75 years old and you are due to undergo a bone marrow transplant from a matched unrelated donor for one of the following:

- ▶ Acute myeloid leukemia (AML)
- ▶ Acute lymphoblastic leukemia (ALL)
- ▶ Myelodysplastic syndrome

If you are receiving a bone marrow transplant for leukemia (AML or ALL), you may be enrolled in this study if you are in remission.

Do you have any of these these conditions?

If you have any of the following conditions, you will not be enrolled in this study:

- ▶ significant cardiac disease
- ▶ chronic obstructive pulmonary disease (COPD)
- ▶ impaired liver or kidney function
- ▶ any disease of the central nervous system
- ▶ Hepatitis B
- ▶ Hepatitis C
- ▶ HIV positive

To join this trial, you must be able to live at home and care for yourself.

Turn the page to learn about the treatments on this trial.



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PLAIN LANGUAGE SUMMARY CONTINUED

What are the treatments on this trial?

The standard of care for the prevention of GVHD -- **methotrexate** and **tacrolimus** -- will be given to all patients on this trial. You may also be given **atorvastatin**. The schedule of treatments is described below:

Before the Bone Marrow Transplant:

- ▶ You will take **tacrolimus** by mouth once per day starting **two days before** the transplant.
- ▶ Additionally, you may be selected to take **atorvastatin** by mouth once per day starting **14 days before** the transplant.

After the Bone Marrow Transplant

- ▶ You will be given **methotrexate** by intravenous infusion **1, 3 and 6 days** after the transplant.
- ▶ You will continue to take **tacrolimus** by mouth once per day for **6 months** after the transplant.
- ▶ Additionally, you may be selected to take **atorvastatin** by mouth once per day for **1 year** after the transplant.

Blood tests will be required if you join this study. One or more bone marrow biopsies may be required.

