Clinical Trial Information

Thank you

for thinking about participating in this study. The information presented here is to support your discussions with your doctor about this study.

Pharmaceutical companies use medical research studies like this one to learn more about investigational medications. These studies help to determine if investigational medications work and are safe to use.

The results of this study will provide additional information about how safe and effective this investigational treatment may be in people with Multiple Myeloma. By taking part in this study, you will be making an important contribution to Multiple Myeloma research.

For more information,
talk to your study doctor or
Contact

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What requirements are in place to help protect clinical trial participants?

Regulations and policies have been developed to help protect the rights, safety, and well-being of people who take part in clinical research studies and to help ensure that these studies are conducted according to strict scientific and ethical principles.

Before a clinical trial can begin, a review board must review and approve the study. This group is called an Institutional Review Board, or an IRB, and is comprised of doctors, scientists, and members of the community.

What is the informed consent process?

Since many clinical trials involve new drugs or test existing drugs in new ways, there are risks associated with participation. It is important that you understand these risks before agreeing to participate. The possible benefits and risks should be discussed with your study doctor. You are encouraged to bring up any concerns you may have and to ask as many questions as you like.

Once you've had an opportunity to ask questions and if you decide to become a study participant, you will be asked to sign an informed consent form. Informed consent is a process through which you learn the important facts about a clinical trial to help you decide whether or not to participate. You will receive a copy of the informed consent form to take with you.

Can I leave the study if I change my mind?

Yes. You can choose to leave the study at any time — either before it starts or during the study. If you decide to leave the trial, it is important to get information from your study doctor about how to leave the study safely. Your doctor will still provide care for you if you leave the study at any time.

What are my options if my health declines while participating in the study?

If your health declines while you are participating in the study, your study doctor will determine if discontinuing your treatment is appropriate and will discuss next steps with you. Your doctor will continue to provide health care to you regardless of whether or not you complete the study.

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A Clinical Trial for Multiple Myeloma

What is Multiple Myeloma?

Multiple Myeloma is a cancer formed in the plasma cells. Normal plasma cells are found in the bone marrow and these cells are an important part of the immune system. Multiple Myeloma causes cancer cells to accumulate in the bone marrow, where they crowd out healthy blood cells. Multiple Myeloma is considered the second most common cancer of the blood, accounting for 10% of all diagnosis. Multiple Myeloma primarily affects elderly individuals with an average age of diagnosis around 70 years of age.

What is immunotherapy?

Immunotherapy is a type of therapy that may help the body's immune system attack cancer cells. The investigational immunotherapy drug used in this study is called pembrolizumab (or MK-3475) and targets a protein called PD-1 found on some cells of the immune system. Pembrolizumab blocks the interaction of PD-1 with another protein called PD-L1, sometimes found on tumor cells. Blocking this interaction may help the immune system recognize tumors and attack them.

Why is this study being done?

This study is being done to evaluate the safety, tolerability, and anti-tumor activity of pembrolizumab and to evaluate the disease response and progression in patients with Multiple Myeloma.

If I participate, what will happen during visits?

Initially, you'll undergo tests to determine if you're eligible for the study and provide a bone marrow sample or aspirate material for disease assessment. Procedures completed during routine study visits may include blood tests, physical exams, administration of medication(s), and sometimes imaging scans. The frequency of study visits will depend on your health status.

Since the study is being conducted to help determine the safety and effectiveness of the investigational immunotherapy, it will be important for your study doctor to maintain contact with you, even after you've completed study related visits. Please be sure to ask your study doctor any questions you might have related to procedures completed during study visits and the frequency at which they will occur. Additional requirements for participating in the study will be explained to you by your study doctor.

What study medications will I receive?

Patients who participate in the study will be randomly assigned (like flipping a coin) to one of two study groups. They are:

1) Investigational group: you will receive Pembrolizumab + Lenalidomide and Dexamethasone.

OR:

2) Control group: you will not receive Pembrolizumab but will receive Lenalidomide and Dexamethasone.

You will have an equal chance (half/half) of being assigned to either one of the two groups.

Who can participate?

In order to be eligible to participate in this study you must:

- Be at least 18 years old
- Have a confirmed diagnosis of active multiple myeloma and measurable disease
- Must not be eligible to receive treatment with your own stem cell transplantation
- Be able to provide a bone marrow sample or aspirate material for disease assessment

There are other eligibility requirements that you must meet in order to participate. You and your study doctor should discuss them to help decide if this study might be a good option for you.