EAA232 Study

Do you have high-risk multiple myeloma that has returned or is not responding to treatment?

If so, you may be eligible to participate in this study of a potential new treatment.

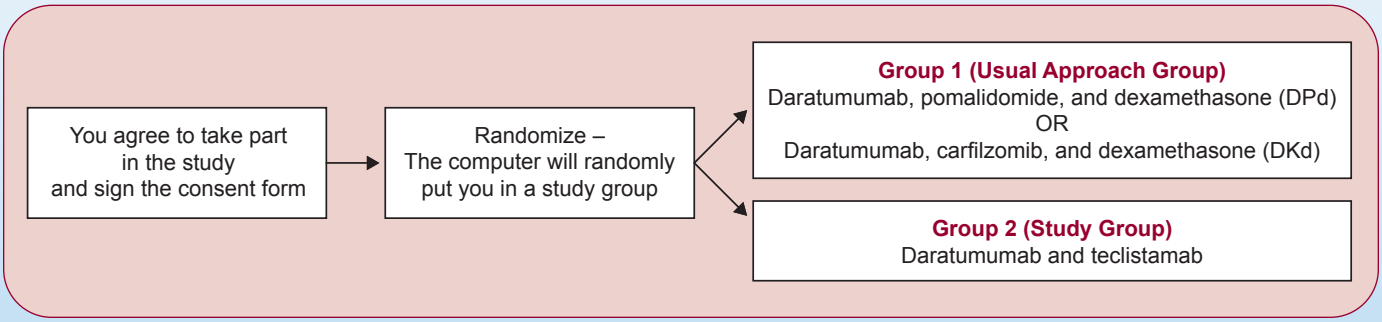
Testing the Investigational Medication Combination of Daratumumab and Teclistamab Compared to the Usual Treatment (Daratumumab, Pomalidomide, Dexamethasone or Daratumumab, Carfilzomib, Dexamethasone) for Patients with High-Risk Multiple Myeloma that is Refractory or in First Relapse

WHY consider participating in this study?

- Research studies are an important way to test the effectiveness of new therapies and approaches to treating cancer.
- The usual approach (i.e., the standard treatment most patients receive) for high-risk multiple myeloma that has returned (relapsed) or not responded (refractory) after initial therapy is treatment with chemotherapy and immunotherapy (such as daratumumab), with or without transplant.
- The purpose of this study is to discover if a new approach using daratumumab in combination with teclistamab improves how well the cancer responds to treatment compared to the existing approaches.
  - Teclistamab is a drug already approved by the Food and Drug Administration (FDA) to treat relapsed or refractory multiple myeloma after multiple prior therapies.

WHAT does this study involve?

- If you are eligible for this study and choose to participate, you will be randomized (randomly assigned by a computer) to one of two groups. You will have an equal chance of being in Group 1 or Group 2.
  - **Group 1** (about 40 people): If you are in this group, you will get the usual medications used to treat your multiple myeloma, which are either daratumumab, pomalidomide, and dexamethasone (DPd), or daratumumab, carfilzomib, and dexamethasone (DKd). The decision between these two treatment types will be determined by your doctor. (Note that these medications are given at various times in 28-day cycles, which will be explained by your doctor).
  - **Group 2** (about 40 people): If you are in this group, you will get the study medications, daratumumab and teclistamab. You will get both medications by an injection under the skin. (These medications are given at various times in 28-day cycles, which will be explained by your doctor).



- You will continue to receive the treatment for as long as you can tolerate the medications and your cancer is responding, or you will stop if your cancer gets worse.
  - » Cancer treatments can cause side effects. Your study doctor will review possible side effects with you, and you can ask questions about them at any time.
- For both groups, after you finish study treatment, your doctor will continue to monitor your condition until 10 years after you started the study. For the first 2 years, you will be evaluated every 3 months, from years 2–5 every 6 months, and from 5 years on, you will be evaluated annually.
  - » Please note, if your study treatment is working and is well-tolerated, you will be followed for as long as you are on treatment, even if that period is beyond 10 years.

WHO will take part in this study?

- Approximately 80 people diagnosed with high-risk multiple myeloma that has returned or is not responding to treatment will take part in EAA232.
  - You must have received only **one** prior line of therapy (i.e., 1 or more cycles of treatment for this cancer, or a series of treatments administered sequentially).
    - » You must not have received daratumumab or isatuximab within 180 days of starting therapy on this study.
- You can decide to stop taking part in EAA232 at any time, for any reason, even after you have enrolled.

WHAT are the costs of taking part in this study?

- Just as if you were receiving the usual care for your cancer, you and/or your insurance plan will need to pay for some or all of the costs of medical care you will receive as part of this study. This includes the costs of tests, exams, procedures, and medications that you get during the study to monitor your safety and prevent and treat side effects.
  - Daratumumab and teclistamab will be provided free of charge. However, you will need to pay for the costs of getting the teclistamab and daratumumab ready and giving it to you.
  - Check with your insurance provider to find out what they will pay for. If you are unsure which costs insurance will cover, ask your doctor or nurse for help finding the right person to talk to.
- Taking part in EAA232 may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer.
- You will not be paid for taking part in this study.

IF you would like more information:

- About the EAA232 study, talk with your doctor, or:
  - Visit www.ecog-acrin.org and search EAA232, then select the link to the EAA232 page.
    - » If you are seeking information about the locations where this study is available, scroll down the page to Locations and Contacts and click the + sign.
  - Call the NCI Cancer Information Service at 1-800-4-CANCER (1-800-422-6237).
- About clinical trials:
  - General cancer information: visit the NCI website at www.cancer.gov
  - Insurance coverage/paying for cancer treatment: www.cancer.gov/clinicaltrials/learningabout/payingfor
- About ECOG-ACRIN:
  - Visit www.ecog-acrin.org
  - For a list of patient resources and links to patient advocacy groups, visit www.ecog-acrin.org/patients/resources

NCI National Clinical Trials Network

ECOG-ACRIN cancer research group