EAA181/EQUATE Study

Do you have newly diagnosed multiple myeloma and are either ineligible for or willing to delay stem cell transplantation?

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

Testing the Use of Combination Therapy in Adult Patients with Newly Diagnosed Multiple Myeloma

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 newly diagnosed multiple myeloma is treatment with a three-drug regimen: lenalidomide and dexamethasone in combination with bortezomib **or** daratumumab. This approach is approved by the Food and Drug Administration (FDA).
- The purpose of EAA181/EQUATE is to find out if patients with a small amount of cancer left after initial treatment (called minimal residual disease [MRD]) could benefit from treatment with all four drugs listed above.

WHAT does this study involve?

- This trial is for patients who are either ineligible for or willing to delay stem cell transplantation. If you decide to take part in this study, first some of your bone marrow will be tested to see if it contains tumor cells with certain informative markers or gene sequences. If you have an informative marker, you will be able to participate in EAA181/EQUATE.
- This study has two groups. Both groups will go through three steps of treatment: induction, consolidation, and maintenance.
  1. **Induction (initial) treatment (9 cycles total, or 36 weeks long):** All participants will take three drugs: lenalidomide, daratumumab-hyaluronidase, and dexamethasone. You will get these drugs either as a pill you take by mouth (lenalidomide, dexamethasone), or by an injection under the skin in your abdomen (daratumumab-hyaluronidase). After 9 cycles of induction treatment, your bone marrow, blood, and urine will be tested. If you are MRD-positive (testing detects that some cancer is still left), you will receive consolidation treatment. If you are MRD-negative (no remaining cancer detected), you will be taken off the EAA181 study, and your doctor will discuss the next steps regarding ongoing treatment with you.
     - » *Note: If recommended, stem cells can be collected for future transplant any time after 4 cycles of induction treatment. You and your doctor will discuss if you are eligible for a future stem cell transplant.*
  2. **Consolidation treatment (another 9 cycles total, or 36 weeks long):** The purpose of consolidation treatment is to kill the remaining cancer cells that are left after induction treatment. You will be assigned by chance (randomized) to one of two groups. You will have an equal chance of being in Group 1 or Group 2.
     - » Group 1 (about 217 people): You will receive daratumumab-hyaluronidase, bortezomib, lenalidomide and dexamethasone. You will get these drugs as a pill you take by mouth (lenalidomide, dexamethasone), or by an injection under the skin (daratumumab-hyaluronidase, bortezomib).
     - » Group 2 (about 217 people): You will continue taking lenalidomide, daratumumab-hyaluronidase, and dexamethasone (i.e., the usual treatment approach, which was given during induction).
  3. **Maintenance treatment (until disease worsens, side effects become too severe, or you wish to stop treatment):** After completing induction and consolidation treatment (a total of 18 cycles or 72 weeks), you will continue to receive daratumumab-hyaluronidase (by injection) every 4 weeks and you will take lenalidomide (by mouth) on days 1 to 21 of each 28-day cycle.
     - » The purpose of maintenance treatment is to slow down the growth of any remaining myeloma cells in your body in order to prevent or delay a relapse.
- 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.

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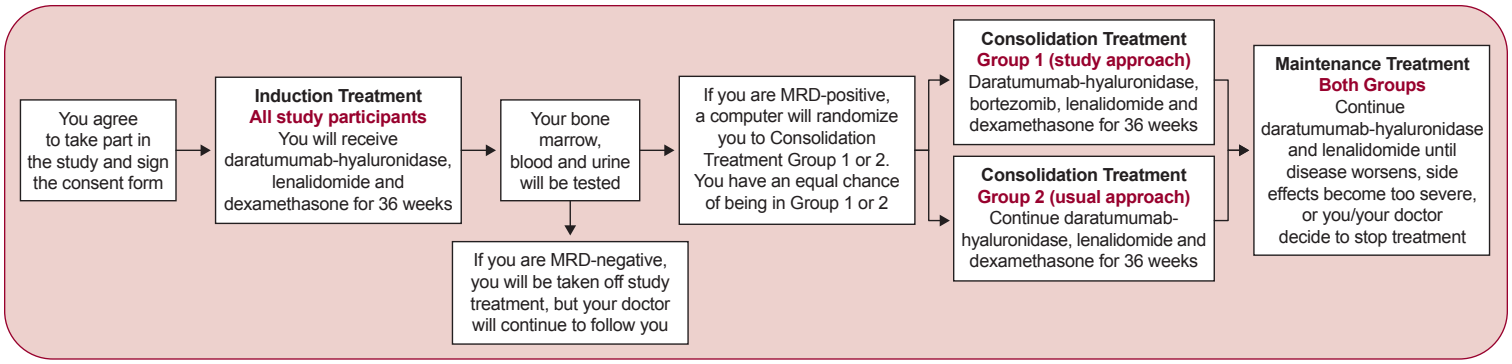

- After you finish study treatment, your doctor and study team will monitor you for side effects and response to treatment.
  - They will check you every 3 months for 2 years from the date you registered for the study. After that, they will check you every 6 months for 2–5 years. Then, they will follow you yearly for 10 years.
    - This means you will keep seeing your doctor for 10 years from the date you registered for EAA181/EQUATE.

WHO will take part in this study?

- Approximately 542 people with newly diagnosed multiple myeloma will take part in EAA181/EQUATE. Out of the 542 participants, researchers expect that approximately 390 of those participants will continue to the second part of the study (i.e., the participants in each group of consolidation treatment).
  - In order to participate in EAA181/EQUATE, you must not previously have had more than 1 cycle of treatment.
- You can decide to stop taking part in EAA181/EQUATE 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 EAA181/EQUATE. 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.
- You and/or your insurance plan will **not** have to pay for:
  - Drugs, tests, exams, and procedures done for research purposes only or that are covered by the study. These include:
    - Daratumumab-hyaluronidase
    - The first two tests performed on the bone marrow samples (i.e., when you first join the study to determine if you can participate, and after you complete induction treatment [after Cycle 9])
- Taking part in EAA181/EQUATE 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 EAA181/EQUATE study, talk with your doctor, or:
  - Visit www.ecog-acrin.org and search EAA181, then select the link to the EAA181 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