EAA173/DETER-SMM Study

Have you been recently diagnosed with high-risk smoldering multiple myeloma?

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

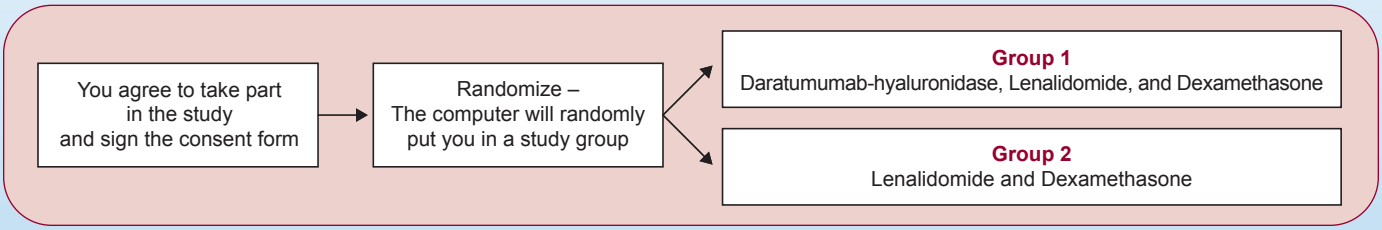
Testing the Addition of Daratumumab to Enhance Therapeutic Effectiveness of Revlimid in Smoldering Multiple Myeloma

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 high-risk smoldering multiple myeloma (SMM) who are not in a study is watchful waiting—your doctor would have you come in periodically for lab tests to determine if you show any signs or symptoms of active myeloma.
  - Recent research that focused on patients with high-risk SMM, however, showed that patients who received a combination of the drug lenalidomide (also known as Revlimid®) and steroids decreased their risk of developing active multiple myeloma; the combination also led to patients living longer.
- The purpose of EAA173/DETER-SMM is to determine whether patients with high-risk SMM live longer when daratumumab (Darzalex Faspro®) is added to lenalidomide (Revlimid®) and dexamethasone (a steroid). The study will also help to determine whether the period of time in which patients are free of active multiple myeloma symptoms differs between the two treatment groups.

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 each group, and you will be told which group you are in. Both groups will receive 24 cycles of treatment (1 cycle = 28 days; note that dexamethasone is only given for 12 cycles). After your study treatment is completed, you will be monitored by your doctor for a total of 15 years.
  - **Group 1** (approximately 144 patients): Participants will receive daratumumab plus lenalidomide and dexamethasone.
    - Daratumumab is given as an injection just under the skin (subcutaneous, or SC) or into a vein (intravenous, or IV):
      - On Cycles 1 and 2, you will be given daratumumab on Days 1, 8, 15, and 22.
      - On Cycles 3–6, you will be given daratumumab on Days 1 and 15.
      - On Cycles 7–24, you will be given daratumumab on Day 1.
    - Lenalidomide is given as an oral medication (by mouth), once a day on Days 1–21 of each cycle.
    - Dexamethasone is given as an oral medication (by mouth) or injection into a vein (IV), on Days 1, 8, 15, and 22 for 12 cycles.
      - After the first 6 cycles, dexamethasone will be reduced by 50%.
  - **Group 2** (approximately 144 patients): Participants will receive lenalidomide and dexamethasone.
    - Lenalidomide is given as an oral medication (by mouth), once a day on Days 1–21 of each cycle.
    - Dexamethasone will also be taken by mouth, once a day on Days 1, 8, 15, and 22 for 12 cycles.
      - After the first 6 cycles, dexamethasone will be reduced by 50%.



- Regardless of the group to which you are assigned, your doctor may recommend that you have what are called "stem cells" collected from your blood. Stem cells are found in very small amounts in the blood and bone marrow normally and help produce blood cells. It is possible that some time in the future, you may want to have stem cells available to use for other cancer treatments such as a stem cell transplant. If your doctor agrees that stem cells should be collected, this procedure will be arranged by your treatment center, and will be attempted between the 4th and 6th cycle of therapy. During the collection process, your study treatments will be paused for up to 6 weeks to allow for the collection, and then you will start again on your assigned treatment.

WHO will take part in this study?

- Approximately 288 people diagnosed with asymptomatic high-risk smoldering multiple myeloma within the last 12 months will take part in EAA173/DETER-SMM.
  - Patients must not have received any prior or current treatment for SMM.
- You can decide to stop taking part in this study 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.
  - You/your insurance provider will **not** have to pay for lenalidomide, or daratumumab (if you are in Group 1), while you take part in EAA173/DETER-SMM. However, you will need to pay for the costs of getting daratumumab ready and giving it to you.
  - You/your insurance provider will **not** have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. These include:

Assessment	Timepoint
^{18}F-FDG-PET/CT	After 12 cycles of treatment At the end of the study treatment
EKG	At the start of the study
Serum Free Light Chain Assay	At the end of each cycle of treatment
Minimal Residual Disease Assessments	Pre-registration and during follow up
Chemistry Labs	During follow up

  - Check with your insurance provider to find out what they will pay for.
- Taking part in EAA173/DETER-SMM 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 EAA173/DETER-SMM study, talk with your doctor, or:
  - Visit www.ecog-acrin.org and search EAA173, then select the link to the EAA173 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