

Clinical trial summary (S2213)

Comparing Dara-VCD and Stem Cell Transplant as Consolidation Treatment for People with Newly Diagnosed AL Amyloidosis



What is the purpose of this clinical trial?

Treatment plans for AL amyloidosis often have 3 steps:

1. **Initial treatment** – the first treatment you receive.
2. **Consolidation treatment** – supports the first treatment.
3. **Maintenance treatment** – given to keep controlling the disease. The dose is often low, and you may get this treatment for a longer time.

This study will compare 2 consolidation treatment options that doctors currently use for AL amyloidosis:

- **Dara-VCD** combines 4 drugs: daratumumab, bortezomib, cyclophosphamide, and dexamethasone.
- **Stem cell transplant** is a procedure that involves collecting stem cells from your blood and storing them for a short time while you have high-dose chemotherapy. The stem cells are then returned to your body.

This trial is set up to find out:

- Which consolidation treatment works better to help prevent AL amyloidosis from causing problems in major organs of the body
- Which consolidation treatment works better to help prevent AL amyloidosis from returning after it is first controlled
- Which consolidation treatment works better to help people with AL amyloidosis live longer
- What side effects people have with each of the consolidation treatments



Why is this trial important?

This trial could change how stem cell transplants and Dara-VCD are used for AL amyloidosis. Treatment plans often include a stem cell transplant when patients can safely receive one. But drug treatments have advanced, and many people have very good responses to Dara-VCD before consolidation treatment.

With today's drugs, doctors don't know if treatment plans should include a stem cell transplant. To determine the best approach, the study doctors will be looking at how well the treatments work against AL amyloidosis and how they affect patients' quality of life.



Who can be in this trial?

This trial is for adults, age 18 or older, with AL amyloidosis.

This trial is for people who:

- Can safely have a stem cell transplant (your doctor determines this)

This trial is not for people who:

- Already received treatment for AL amyloidosis
- Have multiple myeloma
- Have serious heart, liver, kidney or bone marrow problems
- Are pregnant

Talk with your doctor to learn more about who can join this study.



What treatments will I get?

Your treatment in the study will include initial, consolidation, and maintenance treatments.

Initial Treatment

All people in the study receive Dara-VCD for initial treatment.



Consolidation Treatment

If your doctor determines that a stem cell transplant is still a safe option for you after initial treatment, a computer will randomly assign you to one of 2 study groups for consolidation treatment.

Group 1: Dara-VCD

(daratumumab, bortezomib, cyclophosphamide, and dexamethasone)

Group 2: Stem cell transplant

Before the transplant, you will also receive one high dose of the drug melphalan.

Your doctor will not have control over which group you will be assigned to. This helps make sure the study results are fair and reliable.



Maintenance Treatment

All people in the study receive the drug daratumumab for maintenance treatment.



How long will I be in the trial?

In total, your part in the study may last up to 4 years.

Treatment may last up to 3 years. After treatment, you will have follow-up clinic visits to monitor your health.



Are there costs? Will I get paid?

The drug daratumumab is provided free in this study. Consolidation therapy with Dara-VCD and stem cell transplant are both standard treatment options for people with AL amyloidosis. Ask your health care provider and insurance provider about what costs will and won't be covered in this study. You will not be paid for joining the study.



Where can I find more information about this trial?

- Talk with your health care provider
- Call the National Cancer Institute at **1-800-4-CANCER**
- Go to www.ClinicalTrials.gov and search the national clinical trial number: **NCT06022939**
- For a list of trial locations, visit swog.org/NCI-S2213



Key information This trial is for adults 18 years or older being

- **Protocol number:** S2213
- **Full trial title:** A Phase III, Randomized Study of Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone (Dara-VCD) Induction Followed by Autologous Stem Cell Transplant or Dara-VCD Consolidation and Daratumumab Maintenance in Patients with Newly Diagnosed AL Amyloidosis
- **NCT number:** NCT06022939
- **Trial sponsor:** SWOG Cancer Research Network
- **Publishing date:** January 15, 2023

Thank you!

When you join a clinical trial,
you're moving cancer medicine and patient care forward.