Could the RESOLUTION Clinical Trial Be Right for You?

Allogene THERAPEUTICS

What is a Clinical Trial?

Clinical trials are research studies that test new treatments to see if they are safe and effective. Almost all medicines or therapies used today—from antibiotics to advanced cancer treatments—were once tested in a clinical trial.

By joining a clinical trial, you are exploring a potential new treatment for yourself and helping researchers discover better options for future patients living with autoimmune diseases. Participation is always voluntary, and your safety is a top priority. Clinical trials follow strict safety guidelines and are closely monitored by medical experts every step of the way.

How Does the RESOLUTION Trial Work?

The RESOLUTION trial is studying a new type of treatment called ALLO-329, an investigational CAR T-cell therapy. This approach is designed to reset the immune system and stop diseases like lupus, myositis and scleroderma from progressing. It aims to eliminate symptoms, prevent the need for future medication and improve how patients feel and function.

This trial includes several steps:

1. **Informed Consent:** You'll learn all about the clinical trial so you can decide if you want to enroll. If you agree to enroll, you'll sign an informed consent form. Even after you sign the consent form, you can decide to leave the study at any time.

2. **Screening:** During this step, doctors will confirm your diagnosis and check how active your disease is. This screening period lasts up to 30 days. You will have lab tests to ensure the treatment is appropriate and as safe as possible for you. If you qualify and you decide to participate, you will move on to the next step.

3. **Preparation:** If eligible, you may be assigned to one of two groups:
   - **With Lymphodepletion:** You will receive a short course of medicines (cyclophosphamide (sigh-klo-FAWS-fah-myd) alone or combined with fludarabine) to temporarily lower levels of certain immune cells in your body. This helps the CAR T cells work more effectively.
   - **Without Lymphodepletion:** You will not receive these medicines before treatment.

4. **Treatment:** After preparation, you will receive a single infusion of ALLO-329 through an IV (intravenous line). The infusion takes only a few minutes. Afterward, you will stay in the hospital for at least four days so your care team can monitor you closely.

5. **Monitoring:** For the first month after the infusion, you will have frequent check-ups to assess if the treatment is working and to manage any possible side effects.

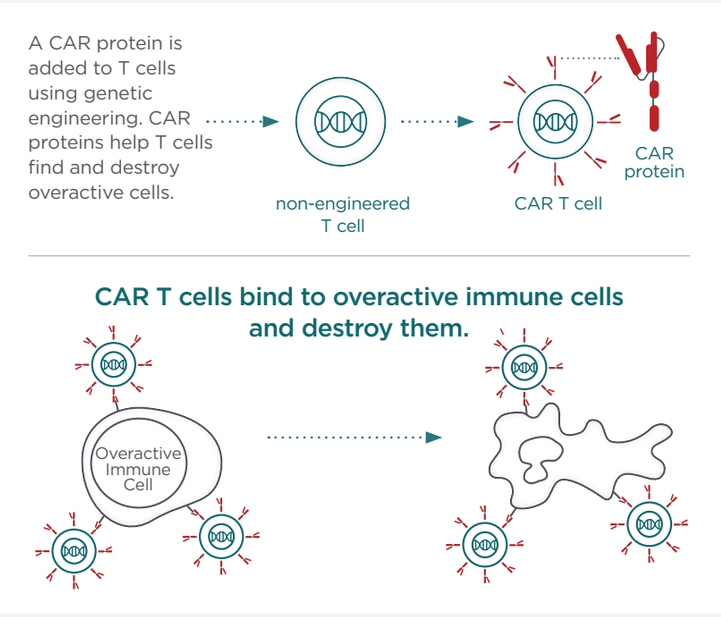
After three months, follow-up visits will become less frequent, similar to the schedule for other patients whose autoimmune diseases are under control. By this point, it is expected that most patients are able to return to a more normal care routine.

What is Allogeneic CAR T-Cell Therapy?

Allogeneic Chimeric (kigh-MARE-ik) antigen (ANN-ti-jin) receptor (ree-SEP-tor) (CAR) T is a kind of advanced immunotherapy treatment that uses specially engineered cells from healthy donors to "reset" the immune system in people affected by autoimmune disease. These donor cells are modified to target and eliminate overactive immune cells that drive disease, allowing the immune system to rebuild itself in a healthier, more balanced way.

Unlike other CAR T therapies, which require collecting and modifying a patient's own cells, allogeneic CAR T cells are pre-made and ready to use, allowing for faster treatment.

This approach is being studied in the RESOLUTION trial using ALLO-329, with the goal of achieving long-lasting remission and reducing the need for daily medications.



Who Can Join the RESOLUTION Trial?

To participate in the RESOLUTION trial, you must:

- Be at least 18 years old and no older than 70 years old.
- Have a confirmed diagnosis of lupus, myositis, or scleroderma
- Meet specific criteria related to the activity level of your disease.
- Have continued disease activity despite prior treatments.
- Have the ability to stay within 2 hours driving distance of a study site for 35 days.

Being close to a trial site ensures you can attend frequent check-ups and close monitoring during the early stages of the study.

What Are the Potential Benefits and Risks?

The goal of the RESOLUTION trial is to assess a new treatment to potentially stop autoimmune diseases and improve quality of life. While this treatment is still being studied, early research suggests it may provide long-lasting, drug-free remission. As with any clinical trial, there are risks, including possible side effects from the CAR T-cell therapy. Your care team will discuss these risks with you and provide support throughout the trial.

Side effects may range from mild to serious or even life threatening. Some side effects might require treatment, others may not. Your doctor will be available to address them as needed. It is important to tell your doctor about any changes or new symptoms you experience during these visits. Your care team will partner closely with you to minimize and address risks promptly.

Why Focus on Autoimmune Diseases?

Autoimmune diseases occur when the immune system mistakenly attacks healthy parts of the body. While current treatments aim to control the disease, they sometimes fail to stop it from getting worse. These treatments can also bring challenges, like significant side effects or the need for lifelong medication.

The RESOLUTION trial is studying whether ALLO-329 can address the root cause of autoimmune diseases by "resetting" the immune system. The goal is long-lasting remission without the need for daily medications.

Scleroderma

What is Scleroderma?

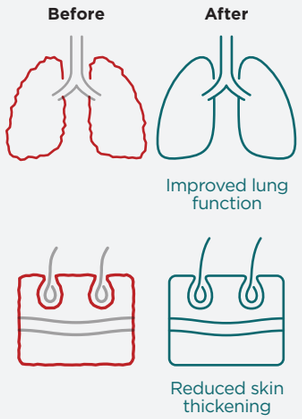
Scleroderma is a rare autoimmune disease that causes hardening and tightening of the skin and connective tissues. It can also affect internal organs like the lungs, heart, and digestive system, leading to serious complications. Symptoms often include thickened skin, joint pain, and difficulty breathing.

How Could a CAR T-Cell Therapy Help?

The RESOLUTION trial is testing whether an "off-the-shelf" CAR T-cell investigational therapy can reset the immune system and halt the progression of scleroderma. By targeting the immune cells driving the disease, this treatment aims to:

- Improve lung function and reduce breathing difficulties.
- Reduce skin thickening and joint pain.
- Slow or stop disease progression, offering hope for long-term relief.

Researchers will focus on how the treatment impacts lung function, skin symptoms, and overall disease activity.



Learn More

If you are interested in the RESOLUTION trial, talk to your doctor or visit the Allogene website for more information.

For additional resources, visit:

Allogene Therapeutics
allogene.com

Scleroderma Foundation
scleroderma.org

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