



# DAISY is a clinical trial for people who have been diagnosed with systemic sclerosis

You might be able to take part if you:

- ✔ Have been **diagnosed with systemic sclerosis** in the past 6 years
- ✔ Are between **18 and 70** years old

## What's the purpose of the trial?

We want to find out whether an investigational drug called **anifrolumab** may be a safe and effective treatment for people with systemic sclerosis.

### What is anifrolumab?

It's a type of drug that we think may help to reduce inflammation and improve symptoms of systemic sclerosis.

In this trial, anifrolumab will be given as an **injection, once a week**. You or your caregiver may get training so you can have these injections at home. If eligible, those who take part in the full trial will get anifrolumab for **at least 1 year**.

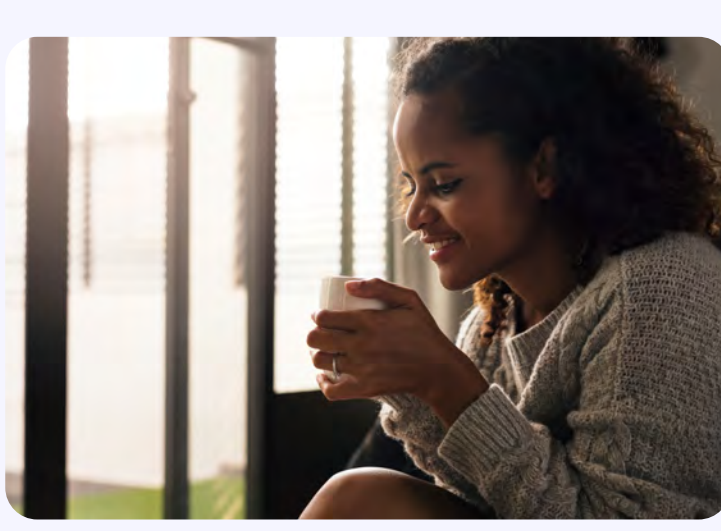
Throughout the trial, you'll be able to **keep taking regular medications for systemic sclerosis**.

You can find out more about anifrolumab in our **trial pamphlet**.

## What can I expect if I take part?

If you do join the trial, you may take part for **up to 2.5 years**. In total, you'll be asked to come for **up to 17 clinic visits**.

The trial is split into **4** different parts. Keep reading for more information about **what** each part might involve, and **why**.



## Screening

Between 2 and 6 weeks

### What

At least 1 visit to the clinic for tests and assessments (including heart and lung tests) **before** you can get the trial drug.

### Why

To help keep you safe by making sure you meet all the trial criteria.



## Trial Treatment - Part 1

Up to 1 year

### What

If you meet the trial criteria, you'll get either **anifrolumab** or a **placebo**, once a week, and have visits every few weeks. You'll have up to 9 visits in total.

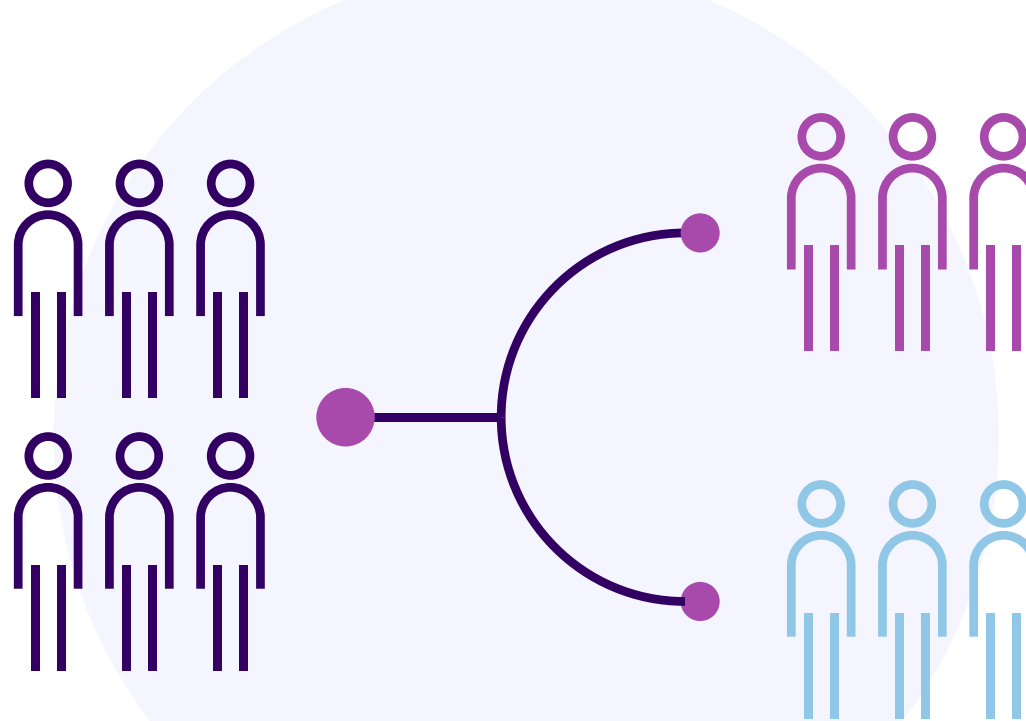
### Why

Comparing anifrolumab with a placebo will help us find out more about how safe and effective it is.

### What is a placebo?

The placebo looks the same as anifrolumab, and is given in the same way, but it does not have any medicine in it. It will help us understand whether anifrolumab is having an effect on your condition.

Even if you're in the placebo group, you will be able to keep taking other treatments for systemic sclerosis. The doctor will discuss this with you in detail.



## Trial Treatment - Part 2

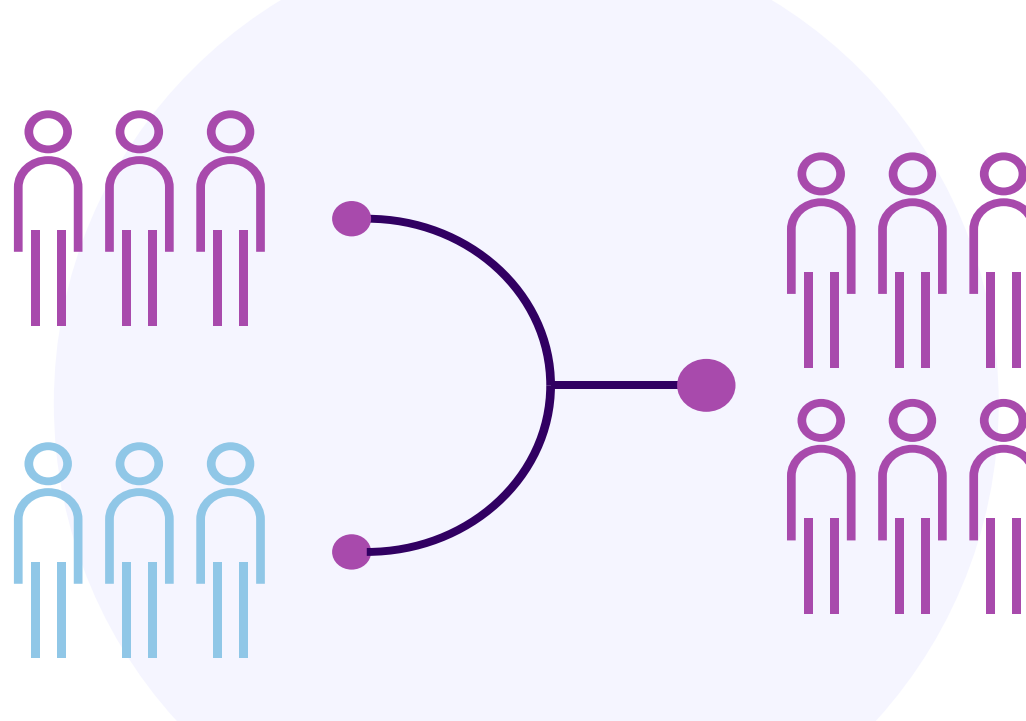
1 year

### What

Everyone who is eligible for Part 2 will get **anifrolumab**, once a week, and have visits every few weeks. You'll have up to 6 visits in total.

### Why

So we can find out more about how safe anifrolumab is, long-term.



## Follow-up

3 months

### What

One final visit, 3 months after your last dose of treatment.

### Why

So we can check on your long-term health and well-being.



### Want to find out more?

You can find a lot more information about the trial and what to expect in our **trial pamphlet**.

You can also read detailed information about the trial on the [clinicaltrials.gov](https://clinicaltrials.gov) website, using the ID number: **NCT05925803**

[Download pamphlet](#)

## Your questions about the trial

This section has other important details about the trial, to help you decide if it's right for you.

### Why do I need to come for clinic visits?

The trial doctor needs to closely monitor you while you're getting the trial drug. This means you will have visits with a doctor **more often** than you would outside of the trial.

Because we need to do some extra tests and assessments, the visits may take a bit longer than you're used to. Visits should usually only take 1 to 2 hours, but this may depend on the clinic. You will not need to come for any overnight stays.

When we're matching you with a trial, we'll always try to make sure it fits with your schedule and personal preferences.

### What tests and assessments will I have?

You'll keep having **all** of your regular tests and assessments as part of your routine care.

At certain times, as part of the trial, you'll also have:

- Heart tests, like ECGs (electrocardiograms) and ECHOs (echocardiograms)
- HPV or pap smear test
- Chest CT (computed tomography) scans and X-rays
- Lung tests
- Extra blood tests

These tests are important to monitor your health and well-being before and while you take the trial drug.

### Will I definitely get anifrolumab?

This trial has **2 treatment parts**:

- In **Part 1**, you'll have a **1 in 2 (50%) chance** of getting anifrolumab (and a 1 in 2 chance of getting a placebo)
- In **Part 2**, **everyone who is eligible** will get anifrolumab

This means that everyone who completes Part 1 may be eligible to get anifrolumab for **at least 1 year**.

### What previous research has been done on anifrolumab?

Anifrolumab has already been tested in an early (phase 1) trial for people with systemic sclerosis, and in trials for people with the condition systemic lupus erythematosus (SLE). This means we have quite a lot of information about how it works in the body, and its possible side effects. But we still need to find out more about how safe and effective it is for people with systemic sclerosis.

### Does anifrolumab have any side effects?

Because anifrolumab works on the immune system, it may make infections like cold, flu, chest infections, and shingles (herpes zoster) more likely. As with any medicine, there is also the risk of an allergic reaction.

Before you decide whether to join the trial, the doctor will give you an informed consent form (ICF) with a full list of side effects, and discuss them with you in detail.

### Can I keep taking my regular medications for systemic sclerosis?

We understand you may be concerned about taking an experimental treatment or a placebo.

To help manage your symptoms, you'll be able to **keep taking** certain approved medications throughout the trial. The doctor will discuss this with you in detail and let you know if there are any medications you need to stop taking.