jasmine

A new clinical study in juvenile myositis, polymyositis, and dermatomyositis

A simple guide to help you decide if **JASMINE** is right for you

Study code: D3463C00003 Version no.: 1.01 Date: 03/28/2025 US-enUS

What is this study about?

JASMINE is a clinical study looking at whether a new treatment called **anifrolumab** (anee-fro-lu-mab) can improve the symptoms of **juvenile myositis, polymyositis, or dermatomyositis**.

You have been given this pamphlet because your doctor thinks the study may be of interest to you. Please continue to read for more details about what the study will involve.

A clinical study is a type of research

It explores whether an experimental treatment is safe and works in humans. It is just one part of a long, careful research process. Your doctor may give you a separate leaflet with more information about clinical studies and why they are carried out.

If you are interested in joining JASMINE, please speak with your doctor. They will be able to provide more information and help you decide what is best for you.

Taking part is entirely your choice, and you can stop at any time.

Who can join this study?

You may be able to take part in JASMINE if you:

- Are 18–70 years of age at the time of joining the study
- Have been diagnosed with juvenile myositis, polymyositis, or dermatomyositis
- Do not have other conditions affecting your muscles
- Have been told you are receiving suitable medication for taking part in the study

There are other criteria to check if the study is the best fit for you. Your doctor will discuss these with you in more detail.

What is anifrolumab?

Normally, your **immune system** is like your personal army inside your body. It is constantly ready to jump into action and protect you from anything that is not supposed to be in there, such as viruses and bacteria that cause infection.

Different parts of the immune system help to keep your body healthy. One of these parts is a type of messenger called an **interferon**. Interferons help to control the immune system and tell it where to act.

Juvenile myositis, polymyositis, or dermatomyositis

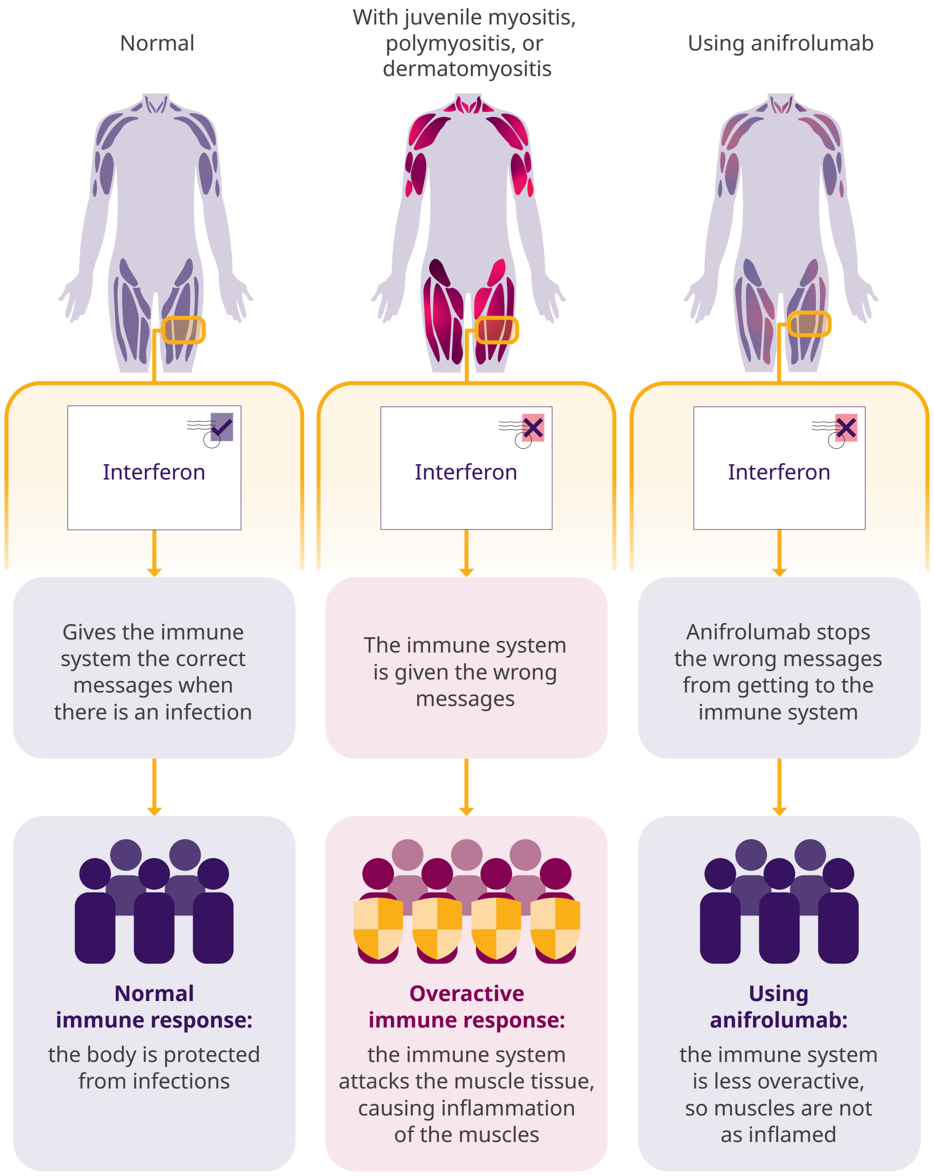
In juvenile myositis, polymyositis, or dermatomyositis, your immune system becomes overactive. It thinks the muscle tissue is something not recognized in your body and overreacts. This causes your muscle tissue to become inflamed. This is thought to happen because interferons are not working properly in juvenile myositis, polymyositis, or dermatomyositis.

Using anifrolumab

Anifrolumab is a medicine that reduces the overactivity of the immune system by blocking the action of some interferons.

In this study, we want to see if blocking these interferons with anifrolumab may help to better control juvenile myositis, polymyositis, or dermatomyositis.

How does anifrolumab work?



Normal	With juvenile myositis, polymyositis, or dermatomyositis	Using anifrolumab
Interferon ✓	Interferon ✗	Interferon ✗
Gives the immune system the correct messages when there is an infection	The immune system is given the wrong messages	Anifrolumab stops the wrong messages from getting to the immune system
Normal immune response: the body is protected from infections	**Overactive immune response:** the immune system attacks the muscle tissue, causing inflammation of the muscles	**Using anifrolumab:** the immune system is less overactive, so muscles are not as inflamed

What will happen if I take part in the study?

During the study, you will be closely monitored by the study team. If you decide to take part, you will be in the study for around 1.5 years.

The study is divided into 3 periods:

Screening
Up to 6 weeks

↓

Treatment
Part 1: 6 months | Part 2: 7 months

↓

Follow-up
3 months

Screening

Before you can join, you will be asked to come to the study clinic to make sure the study is right for you. This is called **screening**.

During this period, you will be asked to attend 1 clinic visit (or more if needed) to have some tests and assessments, including:

- Physical checks of your body and muscles
- Electrocardiogram (ECG)*
- Checks of your vital signs (blood pressure, heart rate, breathing rate, body temperature)
- Lung tests
- A CT† scan of your chest

*ECG is done to check your heart's rhythm and electrical activity. †CT (computerized tomography) scan uses X-rays and a computer to create detailed images of the inside of the body.

Blood and urine samples

Monitoring your movement[‡]

Questionnaires

You may also be asked for a sample of your muscle tissue at the start of the study. This is known as a **muscle biopsy**. It will be optional for some people, and your study doctor will let you know if it is needed for you.

There will also be other assessments. Your study doctor will discuss these with you at the clinic visit.

If the study is not right for you, your study doctor will explain the reasons why. You will continue taking your regular juvenile myositis, polymyositis, or dermatomyositis medicines, and the study doctor will talk to you about other possible treatments and care options.

[‡] Not everyone will have their movement monitored. Your study doctor will let you know if this applies to you.

Treatment

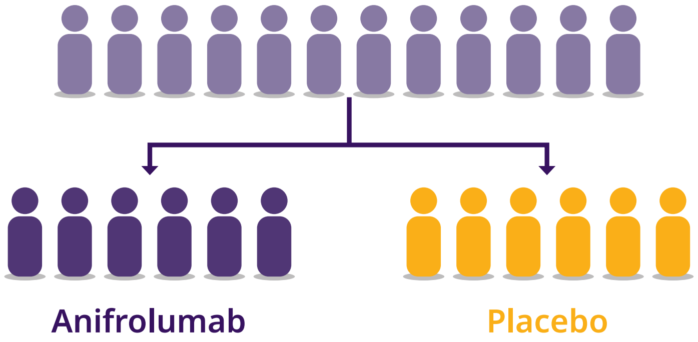
The treatment period is split into 2 parts:

Part 1
You will get either anifrolumab or a placebo

↓

Part 2
You will get anifrolumab

To make sure it is a fair process, in **Part 1** your treatment will be chosen at random by a computer. You will have an equal chance of being in either treatment group. This means you will have a **1 in 2** chance of getting anifrolumab.



Neither you nor the study doctor will know which treatment you are being given. This is important to stop any unfair judgment when doctors are looking at patients' results. *However, if there is an emergency, this information can be found out quickly*.

What is a placebo?

A placebo is something that does not contain any active medicine but looks the same as anifrolumab and is given in the same way.

Placebos are important because they help us to understand whether the new treatment actually works and to check that any benefits seen from taking anifrolumab don't just happen by chance.

Other things to know

- The study treatments will be given as an injection. Sometimes, you or your caregiver will be allowed to inject the study treatment at home. You will receive training on how to do this.
- Please be reassured, you can continue taking certain juvenile myositis, polymyositis, or dermatomyositis treatments for the entire length of the study. Your study doctor will let you know if you will need to stop taking any of your usual medicines.
    - **Even if you are in the placebo group, you will continue to receive medicine for your juvenile myositis, polymyositis, or dermatomyositis**

During treatment

You will be asked to:

- Come to the study site to receive treatment and have tests and assessments to monitor your health, similar to the ones you have during screening
- Use a mobile device to record how you are feeling and any symptoms you may be experiencing
- Come to the clinic **16 times**. These visits will normally be **every 4 weeks**

During Part 2, you will be able to have some of the visits as a telephone call at home, rather than coming to the study clinic. Your study doctor will be able to give you more details about the telephone visits.

Seguimiento

Cuando deje de tomar el tratamiento del estudio, los médicos del estudio le pedirán que visite la clínica del estudio una vez más después de **3 meses** para poder seguir haciendo un seguimiento de su estado y de su salud.

Esta es una parte muy importante del estudio para comprobar que no haya efectos duraderos del tratamiento del estudio.

Mientras dure su participación en JASMINE, el equipo del estudio le hará un seguimiento minucioso. Participar le permitirá recibir un seguimiento y orientación regulares sobre cómo controlar su enfermedad.

Frequently asked questions

Will the study treatment have any side effects?

As with all medicines, the study treatment may have some side effects. Anifrolumab has been approved for adults with lupus but has not yet been investigated for adults with juvenile myositis, polymyositis, or dermatomyositis. Adults with lupus who received anifrolumab did experience some side effects. You may experience none, some or all of these.

If you do join the study:

- Your study doctor will discuss in more detail the side effects to look out for and answer any questions you may have
- You will be closely monitored throughout the study for any signs of side effects or discomforts, so they can be managed as well as possible

Your doctor will be able to provide more information about the possible side effects.

Can I change my mind?

YES — taking part in a clinical study is always your decision. You can stop taking part at any time, for any reason, and it will not affect the care you receive.

What are the costs of taking part?

It will not cost you anything to take part in this study. The study drug, study visits, tests and assessments are all free of charge.

What happens if I can't attend a visit?

This is not a problem — just call your study site and they will arrange a new one for you.

What if I need more support or information?

If you would like more information about JASMINE, please speak to your doctor or contact the study team:

Study coordinator

(for example, a nurse appointed to the study)

Name: ....

Phone: ....

Email address: ....

Address: ....

....

....

....

....

....

We would like to express our deepest thanks to you for considering the JASMINE clinical study. The results from this clinical study could help people, like you, with juvenile myositis, polymyositis, or dermatomyositis in the future.