Would adding to
your current MS treatment
potentially make a difference?

HELP US FIND OUT

THE AFFINITY STUDY

Patient brochure

WHAT IS THE AFFINITY STUDY?

The AFFINITY study is a clinical research study testing the investigational drug (opicinumab) as a potential add-on therapy to disease-modifying therapies (DMTs) in relapsing multiple sclerosis (RMS).

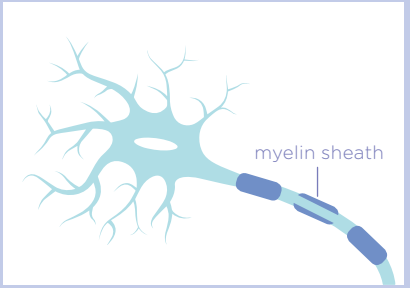
About the investigational drug

Multiple sclerosis (MS) is linked to nerve (brain or spinal cord) damage. In MS, your body's defense system reacts against its own myelin – the 'insulation' that surrounds nerve fibers. When myelin is damaged, the messages between the brain and other parts of the body are disrupted. The investigational drug (opicinumab) is being assessed to see if it can promote regeneration of myelin (called remyelination). Today's MS treatments aim to reduce the frequency and severity of relapses and the accumulation of physical disability by 'dampening' the immune system (in a good way, of course). However, any nerves that are already damaged remain damaged.

The investigational drug in the AFFINITY study is being evaluated to see if it may potentially repair tissue damaged by RMS, and to see if it may have an effect on disability.

The investigational drug was previously assessed in a clinical research study called SYNERGY. In a small sub-set of patients who had received their MS diagnosis no more than 20 years ago (and met other specific criteria in their magnetic resonance imaging, or MRI, scans), initial promising results were seen. Based on the results of the SYNERGY study, we now have information on the appropriate candidates for the investigational drug. We are now looking for people who match these criteria to take part in AFFINITY, our new Phase 2 clinical study being conducted at approximately 150 research centers around the world.

HOW THE INVESTIGATIONAL DRUG MAY WORK



1. Opicinumab is an antibody that targets a protein in the CNS (brain and spinal cord) called LINGO-1
2. LINGO-1 is a part of the process that damages the myelin sheath (the protective covering around the nerves in your CNS)
3. Opicinumab is thought to block the activity of LINGO-1, which may reduce damage to the myelin sheath and affect the progression of MS

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To be eligible for this study you must, in addition to other requirements:

- Be aged between 18 and 58 years
- Have been diagnosed with RMS for no longer than 20 years
- Have been receiving a DMT for at least 24 weeks
- Be able and willing to undergo brain MRI scans

This brochure will provide you with information about clinical research in general, and will describe what this particular study involves and other criteria for eligibility.

Why take part in a clinical research study?

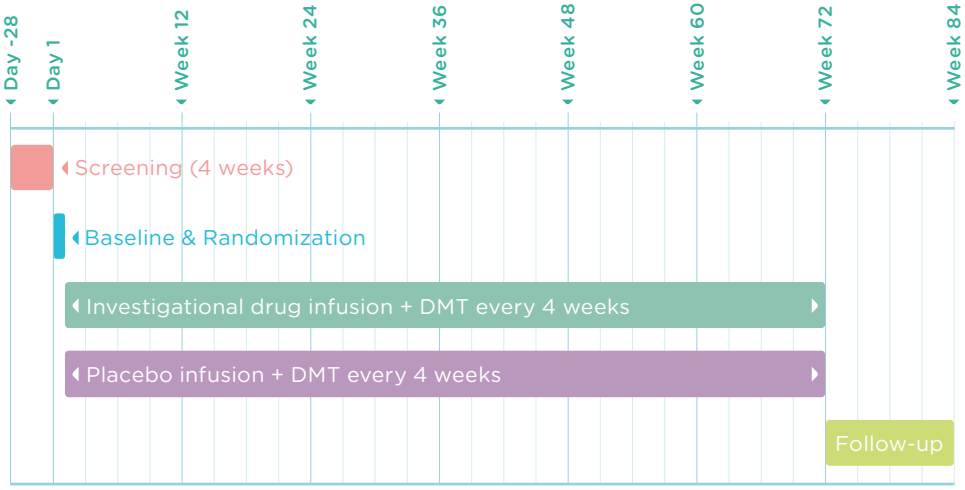
Clinical research studies (also known as clinical trials) can help improve the lives of people all over the world. They are carefully supervised and allow us to answer questions about investigational drugs. People take part in clinical studies for a number of reasons:

- They and the medical community learn more about the condition, which may benefit other sufferers in the future
- Due to the investigational nature of the drug, their health may be monitored more closely than usual whilst on the study

What will this study involve?

The total length of the study is up to 88 weeks (about one and a half years, including a 4-week screening period, a 72-week dosing period and a 12-week follow-up period), during which time you would have around 21 clinic visits. You will be carefully monitored throughout the clinical study using a series of assessments. The assessments will include physical and neurological examinations, cognition (activities of thinking, learning and memory), fatigue, vision, dexterity (hand-eye coordination), mobility (ability to walk), blood and urine tests, heart activity and vital signs checks, and MRI scans. Not every assessment will be performed at each visit.

During the study, there is a 1 in 2 chance that you will receive either the investigational drug or placebo (which looks like the investigational drug but contains no active drug) – neither you nor the study team will know which one you are receiving. Both will be administered via intravenous infusion (a very controlled injection directly into your vein) every 4 weeks at the study center. All participants will continue to take their prescribed DMT throughout the study, and can switch to a different DMT if they need to.



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What are the potential risks?

It is important to remember that, as with any treatment, you can never be sure of the outcome. Your health may improve, it may stay the same, or it could get worse. It is also possible that you may experience unexpected side effects.

However, participant safety is our number one priority during every stage of the study process. It is important to understand that clinical studies are carefully supervised, monitored and documented. Every research study is reviewed and approved by a special group of people called an Institutional Review Board (IRB) or Ethics Committee (EC), which is made up of scientists, non-scientist professionals and members of the public. They make sure that participants' rights are protected and they seek to avoid exposure to unnecessary risks. IRBs and ECs will only approve studies that they think could help answer important medical questions.

While the study is ongoing, a team of study doctors and nurses at the study center will closely monitor your health.

Interested in taking part? What happens next?

If you would like to take part in this clinical research study, the following process will be followed:

Consider the study information and discuss the details with your family and your study doctor if you wish

Contact the study team and schedule an appointment

Review and sign the Informed Consent Form to show that you understand and agree to what the study involves

IF ELIGIBLE

You will begin to take part in the study

IF NOT ELIGIBLE

You will continue with your usual healthcare

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THANK YOU

for considering taking part in the AFFINITY study.

Remember – participation in this clinical study is voluntary. Although others can help you make up your mind, the final decision is yours to make. If you join the study but then change your mind, you are free to leave at any time without affecting your future healthcare options.

Please speak to your physician to find out more information or to be considered for this study. Alternatively, please contact the study team using the contact details below. Thank you for your interest in the AFFINITY study.

[CONTACT BOX]

AFFINITY