The **I TRANSCEND** Study is a phase 2 evaluating the safety, tolerability and effectiveness of an investigational medication in adults who have anti-neutrophil cytoplasmic antibody-associated vasculitis (ANCA Vasculitis). Specifically, the study is looking for people with the ANCA Vasculitis subtypes GPA and MPA.

Sub-types of ANCA Vasculitis in the I TRANSCEND study

GPA: Granulomatosis with polyangiitis
MPA: Microscopic polyangiitis

Medical Terminology Definitions

granuloma: small grouping of white blood cells and other tissue
-tosis: increase or excess
polyangiitis: inflammation of many vessels
microscopic: only visible by microscope

About ANCA Vasculitis

ANCA vasculitis is an autoimmune disease targeting small blood vessels, triggered by ANCAs (Anti-Neutrophilic Cytoplasmic Autoantibodies). These autoantibodies, part of your own body's immune system, attack neutrophils, a type of white blood cell, causing them to attack the small blood vessels, resulting in inflammation known as vasculitis. This condition has different symptoms depending on the organs involved; affected skin vessels can cause rashes, whereas kidney involvement might lead to blood and proteins leaking into urine and decreasing kidney function. Not all individuals with ANCA vasculitis experience the same organ involvement, and the reasons for this difference remain unclear.

What You Should Know about Clinical Research Studies

Clinical research studies aim to answer specific questions about how medicines work in the volunteers who take them. You should feel fully informed about what to expect from your participation in a clinical research study.

Researchers use clinical research studies to:

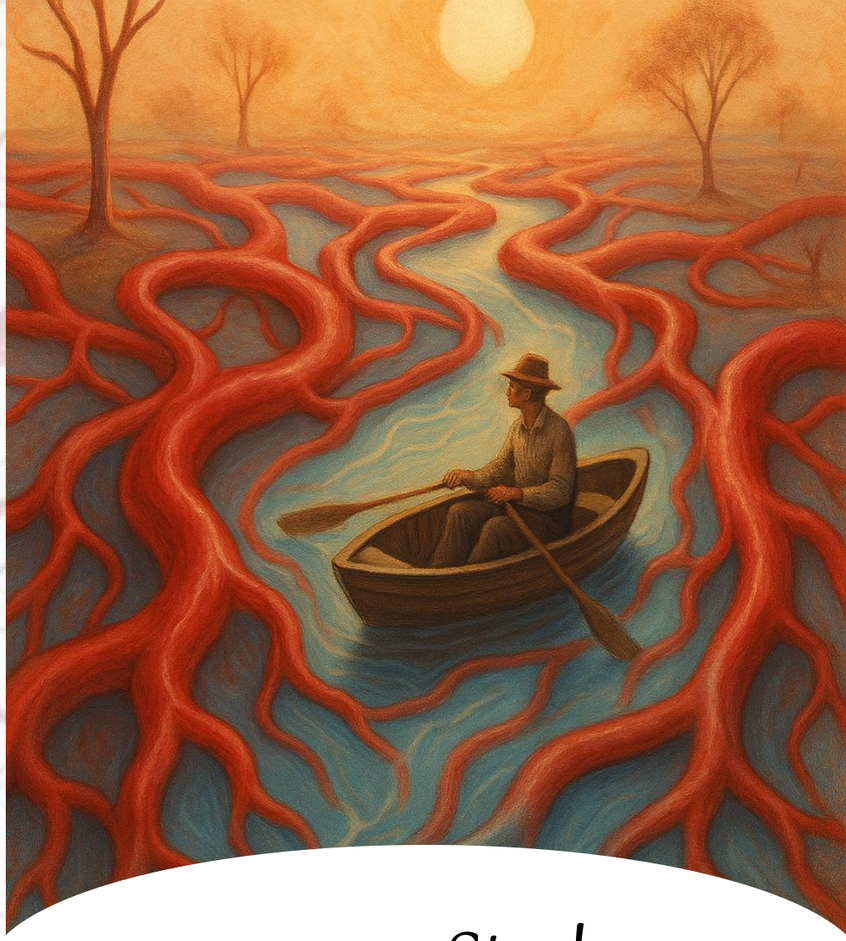
- Answer specific health questions
- Learn about the safety and effects of study treatments
- Help find new ways of using approved medications

All clinical research studies are:

- Developed to protect the rights, safety, and well-being of participants
- Conducted according to strict scientific and ethical principles reviewed and approved by an institutional review board (IRB) or ethics committee (EC)

Participation in any clinical research study is voluntary. The study team will inform you of the potential risks and benefits of study participation, as well as possible side effects. To make an informed decision, talk to your healthcare providers about any questions you may have.

During the study, you will work with a study team that may include study doctors, study nurses, and other research staff. Travel and food reimbursement may be available – please speak with your study doctor to find out.



I TRANSCEND Study

A phase 2 study evaluating an investigational medication in adults who have ANCA-associated vasculitis

ALEXION®
AstraZeneca Rare Disease

About the I TRANSCEND Study

Participation in the **I TRANSCEND** Study may last up to 72 weeks, approximately 1 year and 5 months, and includes 44 study visits in the following periods:

Screening Period: Lasts approximately two weeks and includes one visit. The study team will review your medical history and perform tests to see if you qualify for the study.

Study Treatment: Lasts approximately 52 weeks and includes 40 visits. During this period, you are randomly assigned to a study group to receive either the study medication or a placebo, which looks just like the study medication but contains no active ingredients. The chance of receiving the study medication is 2:1.

The first 26 weeks of the study treatment period includes 27 visits. Depending on the regulations in your country, there may be an option to have some visits conducted in your home by a study nurse or a study team member from your study clinic.

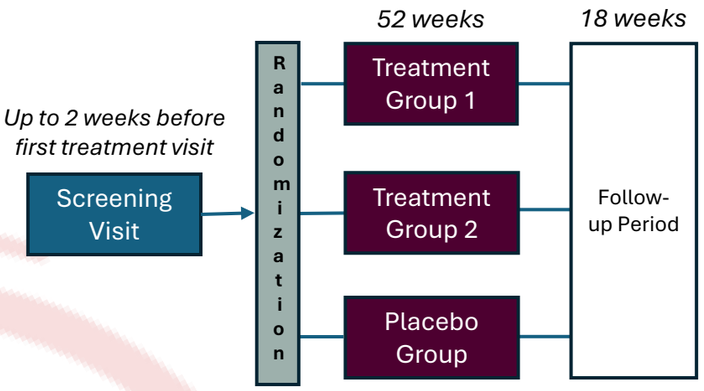
Study Follow-up Period: Three in-clinic study visits across 18 weeks. The visit during week 70 is your end of study final visit.

Your study doctor will instruct you about any current treatments that you are taking. The study team will perform procedures and assessments during study visits to check on your health.

About the Study Medication

The study medication is called Tarperprumig / ALXN1820. It is being used in this study for research purposes only. ALXN1820 has not yet been approved by country-specific regulatory health authorities to be used in treating ANCA Vasculitis, and this is why this study is important. Participants will be randomly assigned to receive either ALXN1820 or the placebo.

ALXN1820 works on a part of the immune system called the **complement system**. ALXN1820 works to slow or turn off the activity of the complement system which may be responsible for the inflammation of the small blood vessels that causes ANCA-associated vasculitis.



Who Can Join?

The **I TRANSCEND** Study is enrolling at around 86 sites across 14 countries. To be eligible for this study, you must:

- Be at least 18 years of age but not older than 80
- Have a new diagnosis of ANCA-associated vasculitis with GPA or MPA subtype
- Have a positive test for either PR3-ANCA or MPO-ANCA antibodies at the screening visit
- Agree to receive treatment with appropriate antibiotics if/while receiving rituximab
- Be willing to be vaccinated against N meningitidis (Meningococcus) if needed

Individuals will be evaluated to determine their eligibility to participate. Those who are eligible and decide to participate will receive the study medication (or placebo), study-specific medical exams, and study-specific laboratory tests at no cost.

If you have questions about participating, please talk to your doctor to see if the **I TRANSCEND** Study is a potential option for you