

Why am I being invited?



You are being invited to participate in this clinical research study because:

- You have been diagnosed with Alport syndrome (AS).
- Your kidneys are showing signs of damage, meaning they're letting protein leak into your urine, which is not supposed to happen.

What is the purpose of the study?

The main purpose of this study is to learn:

- Whether the investigational drug is safe and how it affects the body.
- How the investigational drug works in participants with Alport disease.
- How the investigational drug moves into, through and out of the body.



Potential benefits



- It is not known whether you will receive any benefit from participating in this study.
- You may benefit from the additional medical tests. Your health status will be more closely checked during the time you are involved in the study.
- This study will help doctors learn more about the investigational drug and study whether it works in patients with AS. This information may help patients with AS in the future.

Your rights



- Joining the study is entirely up to you.
- If you decide not to take part in this study, you will still receive your standard medical care.
- Take time to carefully read the information about the study.
- If you join the study, but later decide to stop participating, you will continue to receive standard medical care, and the study doctor will follow up with you on the next steps to take.

The study doctor will take the time to give you a detailed explanation of every aspect of the study, the disease, and the expected effects of the investigational drug. You're welcome to ask the study doctor any questions or request more information at any time.

Study doctor

Contact information

This study is sponsored by Bayer AG,
Germany

IMPORTANT INFORMATION ABOUT PREGNANCY

You'll need to use effective birth control while taking the study treatment and for 3 months after your last dose of the study treatment.

If you are pregnant or breastfeeding, you won't be able to take part in the study.



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ASSESS
STUDY



AN INVITATION TO THE ASSESS* STUDY



Your doctor would like you to consider taking part in a clinical research study.

The ASSESS study is a Phase 2a clinical research study that will evaluate how an investigational drug works in patients with Alport syndrome. Take the time to read this leaflet and the other information that the study team will provide.

*ASSESS (Alport Syndrome Sema3A Efficacy & Safety Study)



What is a Phase 2a study?

Phase 2a studies help determine whether an investigational drug works (efficacy) and what side effects it might cause in a small group of patients. These studies come after Phase 1 studies, which check the drug's side effects in a small number of healthy volunteers.

Which drug is being studied?

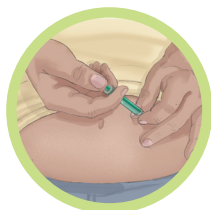


The drug being studied is an investigational drug. Investigational means that it can only be used in clinical research studies. The investigational drug is a monoclonal antibody that blocks a protein called **Sema3A**. **Sema3A** is usually increased in patients with kidney disease and can worsen kidney damage. Researchers will look into whether blocking this protein can help lower the risk of kidney disease progression.

This study will compare the investigational drug to a placebo. A placebo looks exactly like the investigational drug but does not have any medicine in it.



At the start of the treatment, the investigational drug or placebo will be given as an intravenous (IV) infusion (an infusion into one of your



veins) and a subcutaneous (SC) injection under the skin. Afterwards it will be given by SC injection only, once a week.

Potential side effects



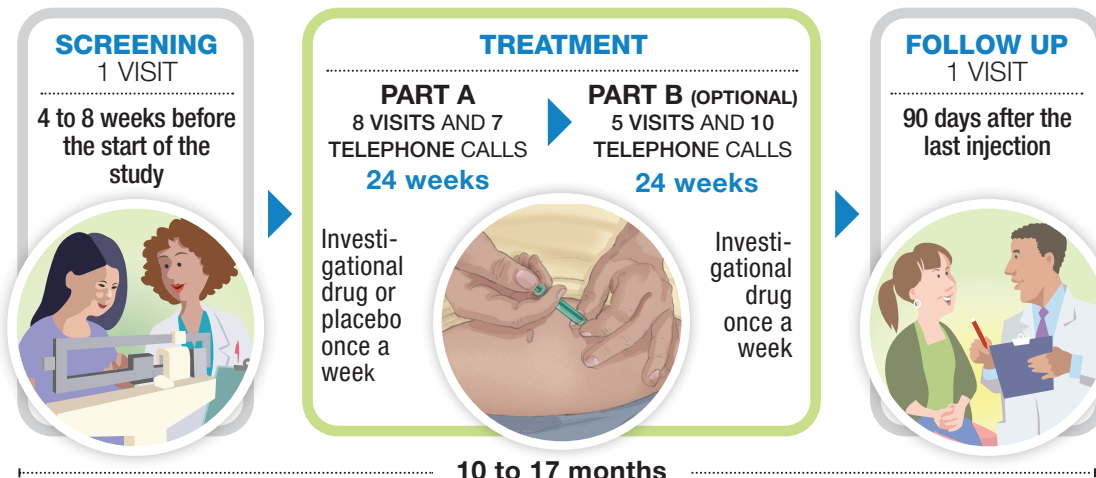
Based on what researchers know about the protein **Sema3A**, doctors expect you may experience some, all, or none of the following side effects:

- Side effects observed in the previous study:
 - Hypersensitivity or allergic reaction to the injection.
 - Mild skin rash or itching at the injection site.
- Other potential side effects:
 - Changes in how you perceive taste.
 - Delayed wound healing.

As with every investigational drug, you need to be aware that there may be side effects that are not yet known. If you experience any expected or unexpected side effects, you should always tell the study doctor.

Please see the Information Sheet for Participants for complete information on the study and potential side effects.

Taking part in the study



Screening: The study doctor will collect information on your health. You will have medical assessments to help make sure that it is safe for you to take part in the study.

Treatment: In the first part of the study (Part A), a computer program will randomly choose whether you will receive the investigational drug or the placebo. Neither you nor the study doctor will know which one you are taking.

After 6 months, you will be invited to an optional extension treatment period (Part B). In this part, all participants will receive the investigational drug.

At the start of both Part A and Part B, you will receive an IV infusion, followed by weekly subcutaneous (under the skin) injections.

Procedures: Throughout the study, you will undergo blood and urine tests, as well as assessments to monitor your heart.

When at home: You'll be asked to give yourself the subcutaneous injection of the study treatment once a week and record each dose on a card. On days when you have a study visit, the injection will be administered at the hospital or clinic instead.

You will receive instructions on how to store the study treatment vials and how to give yourself the injections. The study doctor will also follow up with you by phone.

For each study visit, you'll need to bring three morning urine samples: one from the morning of

the visit and two from the mornings of the two days before.

Your role: You will be responsible for attending all scheduled study visits and calls, administering the study injections as instructed, and informing your study doctor about any new symptoms, health changes, or medications. Please also let any other doctors you see know that you're participating in this study.

Follow-up: You will have a follow-up visit 3 months after the last injection.

If you take part in Part A only, your participation will last between 10 and 11 months. If you also choose to join the optional Part B, your participation may last up to 17 months.

Expert safety review

- This study has been reviewed and approved by regulatory health authorities and by an Independent Research Ethics Committee or Institutional Review Board. This review helps make sure that your safety, rights, and well-being are protected.
- The study doctor, the sponsor, or the Ethics Committee or Institutional Review Board may decide to stop the study treatment at any time if they have concerns about its safety.



During the study, you will continue to take all your usual medications.

