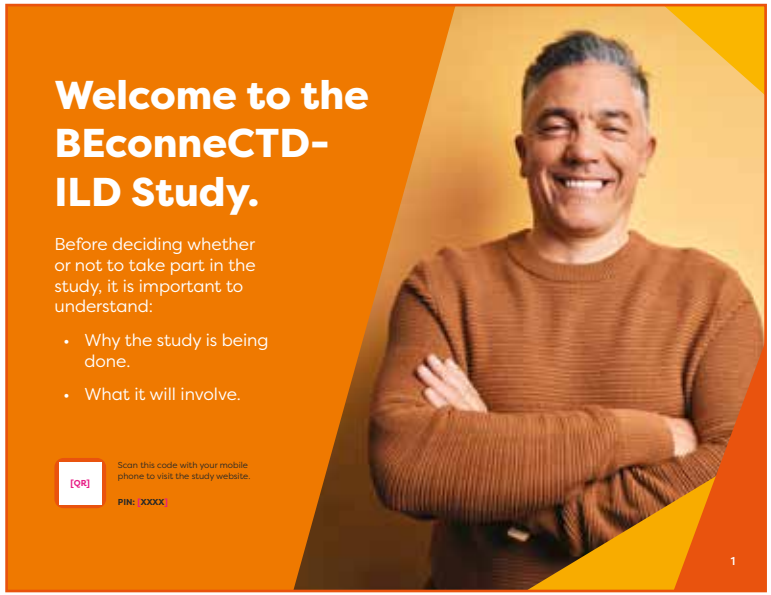
BEconneCTD-ILD

Understanding the BEconneCTD-ILD Study

A clinical research study for adults with interstitial lung disease (ILD) associated with connective tissue disease

Welcome to the BEconneCTD-ILD Study.



Discussion Question

Before we continue, what questions can I answer about your condition or why you have been invited to take part in this study?

- You have been invited to participate in this research study because your doctor has diagnosed you with ILD, or lung fibrosis, associated with connective tissue disease.
- Before deciding whether or not to take part, it is important to understand why the study is being done and what it will involve.
- The first step is to go through an informed consent process, in which the study staff tells you about the study. The goal is to make sure you fully understand the study and what it means to participate. You'll also get a form to read. Signing the form means you give your permission to be part of the study.
- Your decision to take part in this study is voluntary. It is completely up to you. You can change your decision and leave the study at any time.

Welcome to the BEconneCTD-ILD Study.

Before deciding whether or not to take part in the study, it is important to understand:

- Why the study is being done.
- What it will involve.

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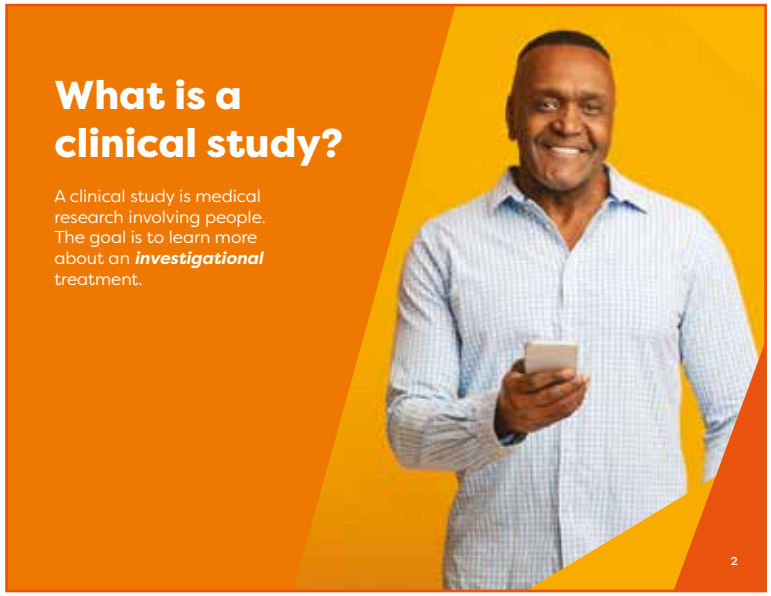
Scan this code with your mobile phone to visit the study website.

PIN: [XXXX]

What is a clinical study?

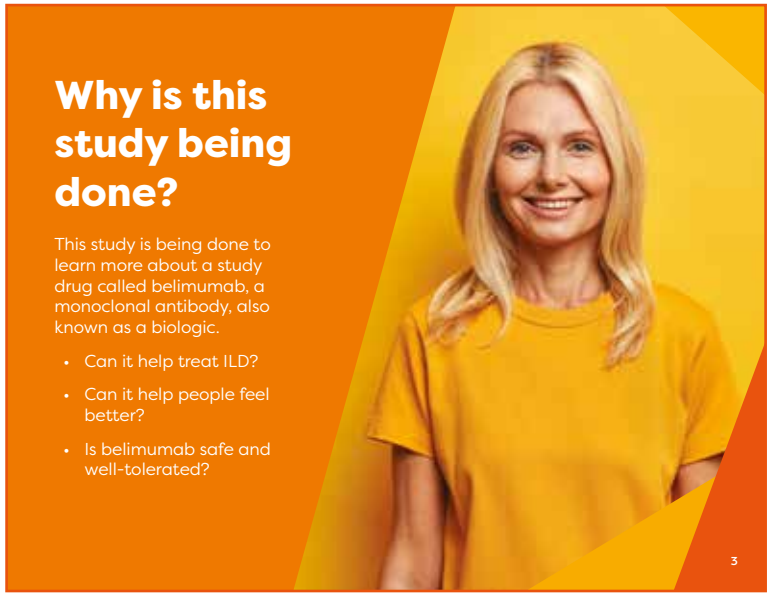


- A clinical study is a medical research study in people.
- Studies help doctors learn more about what a specific treatment does in people with a specific health condition, what side effects can be expected, and whether the treatment can help people with that condition.
- In order to show that a medicine will truly help the patients it's intended for, it has to be tested in a diverse group of people. Clinical studies need volunteers from all different backgrounds, in terms of disease severity, age, sex, gender, ethnicity, and race.
- Some studies, like this one, are done to see if a drug that is already being used for one condition can safely be used for a related condition. Because the drug is not approved for the condition being studied, it is called “investigational” or “experimental,” or simply “the study drug.”

What is a clinical study?

A clinical study is medical research involving people. The goal is to learn more about an ***investigational*** treatment.

Why is this study being done?



- Doctors and researchers are conducting this clinical study to learn more about a study drug called belimumab, a monoclonal antibody, also known as a biologic.
- Belimumab (otherwise known as Benlysta™) has been approved by health authorities. It is available by prescription in many countries to treat active systemic lupus erythematosus (SLE) in adults and children aged 5 years and older and active lupus nephritis (LN) in adults. While different from connective tissue disease, these diseases also occur when the immune system attacks a person's own cells and tissues. Belimumab has not been approved to treat ILD.
- This study is being done to test if belimumab is well-tolerated, helps treat ILD, and helps people feel better.

Why is this study being done?

This study is being done to learn more about a study drug called belimumab, a monoclonal antibody, also known as a biologic.

- Can it help treat ILD?
- Can it help people feel better?
- Is belimumab safe and well-tolerated?

What is the study treatment?

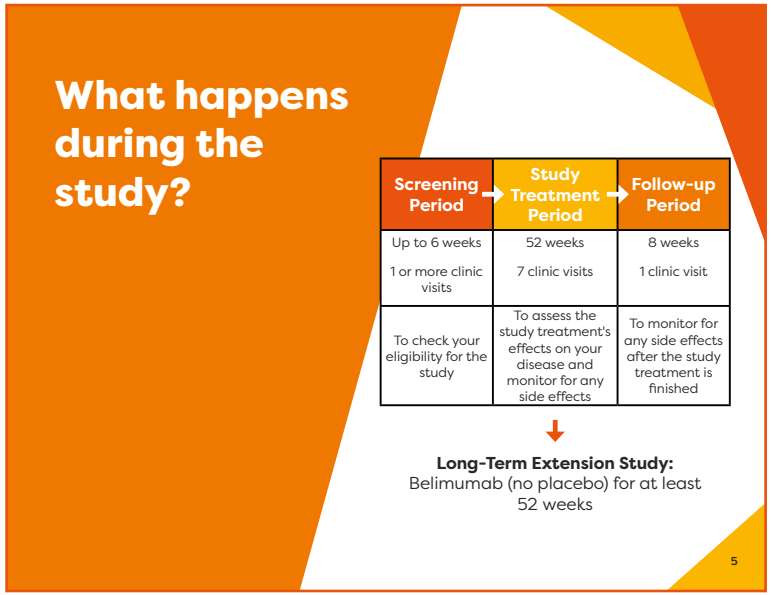
- Belimumab is being compared to a placebo. The placebo looks just like belimumab but contains no active ingredients.
  - → Having some participants take a placebo helps researchers understand the true effects of belimumab.
- You or your caregiver will give you your study treatment (belimumab or the placebo) as an injection under the skin (subcutaneous) once every week.
  - → You will continue to take your usual medicines.
- Whether you get belimumab or the placebo will be determined by chance (using computerized randomization).
- You have an equal chance of being placed in the belimumab group or the placebo group. Neither you nor the study doctor will choose the group.
- The study doctor, you, and your caregiver giving you the injection will not know which study treatment you are getting. This is called double blinding. You and the study doctor will be told only after the study has been completed or in case of a medical emergency.
- The benefits and risks of belimumab will be compared to that of the placebo.

What is the study treatment?

Belimumab OR Placebo
One injection every week for 52 weeks

The benefits and risks of belimumab will be compared to that of the placebo.

What happens during the study?



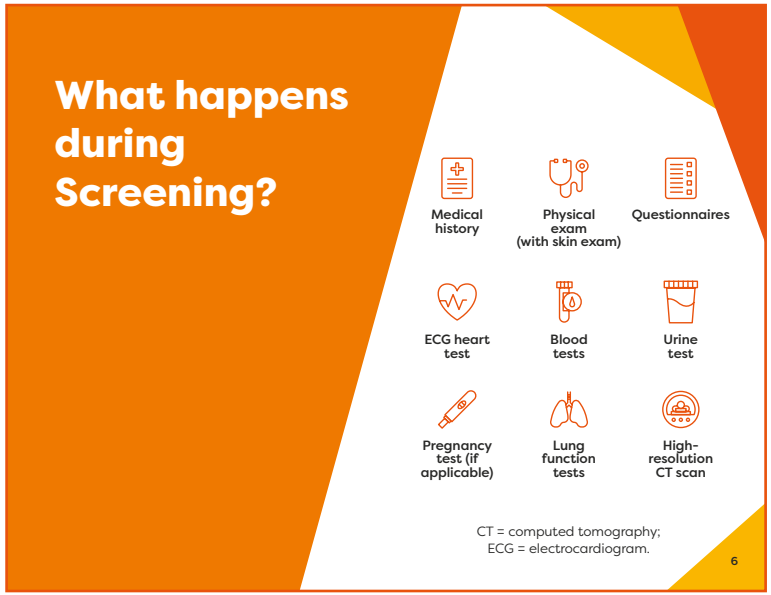
- **Screening:** Before you can take the study treatment, you will need to have a medical review and undergo several medical tests to help the study doctor decide if you can take part in the study.
  - → During Screening, you may need to visit the hospital several times for different tests. Visits may take several hours.
  - → You will need to set up access to an app. You will use the app throughout the study to complete questionnaires, record your injections and pregnancy test results (if applicable), and get important reminders.
- **Study Treatment:** You will take belimumab or a placebo for 52 weeks (1 year). There will be 7 study clinic visits over the course of the 52-week Study Treatment Period.
- **Follow-up:** When the Study Treatment Period is over, you may be asked to return for a Follow-up Visit for your safety.
- **Long-Term Extension Study:** At the end of the 52-week Study Treatment Period, you may be eligible to join a separate Long-Term Extension Study and receive belimumab for at least 52 weeks, regardless of the treatment group you were assigned to in the current study. There will be no placebo.

What happens during the study?

Screening Period	Study Treatment Period	Follow-up Period
Up to 6 weeks 1 or more clinic visits	52 weeks 7 clinic visits	8 weeks 1 clinic visit
To check your eligibility for the study	To assess the study treatment's effects on your disease and monitor for any side effects	To monitor for any side effects after the study treatment is finished

Long-Term Extension Study:
Belimumab (no placebo) for at least 52 weeks

What happens during Screening?



- Screening health checks and tests will include:
  - → Questions about you, your current health, and your medical history.
  - → A complete physical examination including your height, weight, and vital signs (temperature, heart beat, breathing rate, and blood pressure).
  - → Answering questionnaires on an electronic device about your general health, mental health, and your disease.
  - → An electrocardiogram (ECG) to check your heart's rhythm and electrical activity.
  - → Blood and urine samples for lab testing, including a pregnancy test (if applicable).
  - → Lung function testing, which involves breathing air in and out of 2 different devices.
  - → A high-resolution CT scan of your chest to check your lungs.
- You may need to visit the study clinic more than once to complete the Screening tests. Visits may take several hours.

CT = computed tomography.

What happens during Screening?

Medical history

Physical exam (with skin exam)

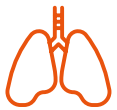
Questionnaires

ECG heart test

Blood tests

Urine test

Pregnancy test (if applicable)

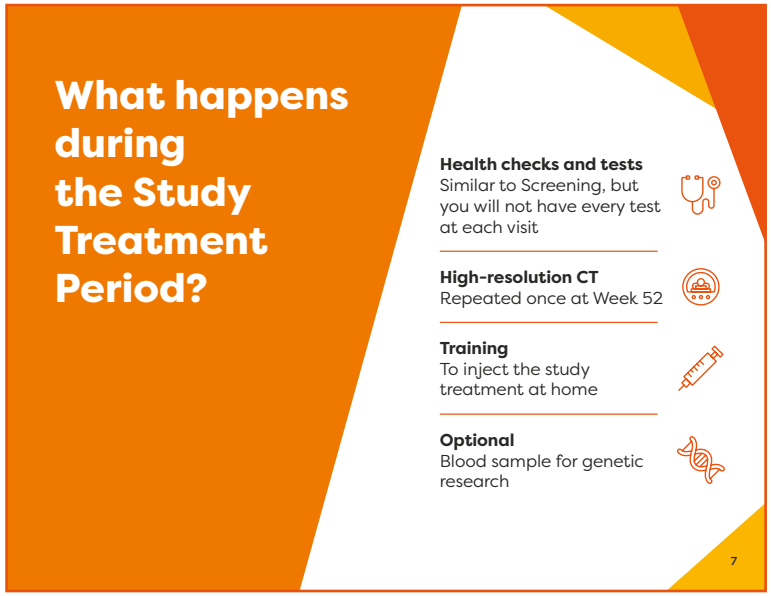


Lung function tests

High-resolution CT scan

CT = computed tomography;
ECG = electrocardiogram.

What happens during the Study Treatment Period?



Discussion Question

In your own words, why is it important for you to attend each scheduled study visit?

- If Screening shows the study is right for you, you will enter the Study Treatment Period and be assigned to a study treatment group (belimumab or the placebo).
- At study visits, you'll have health checks and tests similar to those you had at Screening. You will not have every test at each visit.
- At Visits 1 and 2, the study staff will train you and a caregiver (if applicable) on how to inject the study treatment so you can take it at home. These visits will likely take about 5 hours as you will need to be observed for 3 hours following the injections. Most of the other visits will take between 1 and 3 hours.
- If you have agreed to participate in the optional genetic research study, a separate blood sample will be taken for this purpose.
- If during the study, despite the treatments you are on, your disease gets worse and your doctor thinks it is in your best interest to receive additional medicine for it, you can do so. This is called *escape medication*.

What happens during the Study Treatment Period?

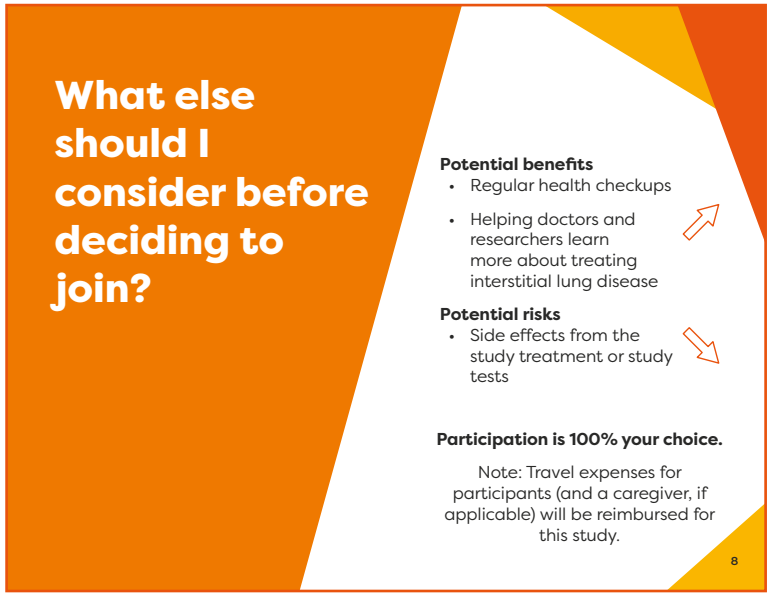
Health checks and tests
Similar to Screening, but you will not have every test at each visit

High-resolution CT
Repeated once at Week 52

Training
To inject the study treatment at home

Optional
Blood sample for genetic research

What else should I consider before deciding to join?



Each clinical study has potential benefits and risks.

Potential benefits

- During this study, you will have regular health checkups.
- We cannot guarantee that you will benefit from taking part in this study. However, knowledge gained from this study may help doctors and researchers learn more about treating ILD.

Potential risks

- You could have side effects from the study treatment or study tests. Read the Informed Consent Form for more details about possible side effects, and ask any questions you may have.

Remember:

- Your participation in the study is voluntary and you can leave at any time for any reason.
- There is a time commitment to come to study visits and complete all study requirements.
- If you want to leave the study, please let the study staff know. We may ask you to come back for one or more visits for your safety.

Note: Travel expenses for participants (and a caregiver, if applicable) will be reimbursed for this study.

What else should I consider before deciding to join?

Potential benefits

- Regular health checkups
- Helping doctors and researchers learn more about treating interstitial lung disease

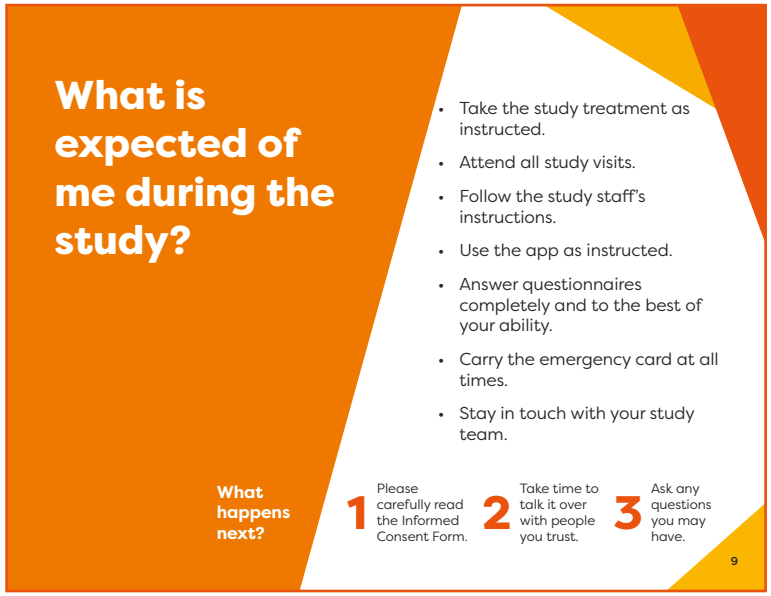
Potential risks

- Side effects from the study treatment or study tests

Participation is 100% your choice.

Note: Travel expenses for participants (and a caregiver, if applicable) will be reimbursed for this study.

What is expected of me during the study?



- Take the study treatment as instructed.
- Attend all study visits.
- Follow the study staff's instructions.
- Use the app as instructed.
- Answer questionnaires completely and to the best of your ability.
- Carry the emergency card given to you by the study staff at all times.
- Stay in touch with your study team and let them know if anything changes with your health or contact information.

What happens next?

- Please carefully read and review the Informed Consent Form.
- Take time to talk it over with family, friends, and people you trust to help you make medical decisions.
- Ask any questions you may have, including questions about study-related expenses and your personal health information.
- If you agree to join, sign the Informed Consent Form. A study staff member will schedule a Screening Visit.

What is expected of me during the study?

- Take the study treatment as instructed.
- Attend all study visits.
- Follow the study staff's instructions.
- Use the app as instructed.
- Answer questionnaires completely and to the best of your ability.
- Carry the emergency card at all times.
- Stay in touch with your study team.

What happens next?

1. Please carefully read the Informed Consent Form.
2. Take time to talk it over with people you trust.
3. Ask any questions you may have.