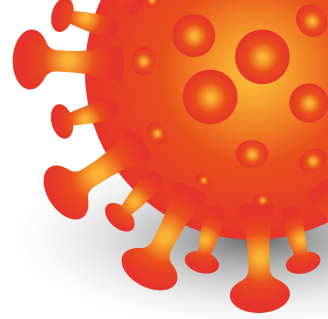
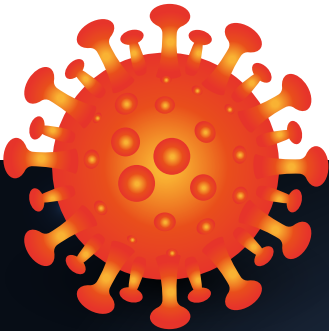


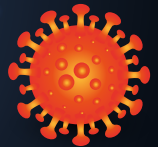
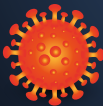
STORM CHASER



Participant Study Guide



This Study Guide contains important information about the STORM CHASER Study. Please keep it in a safe place.

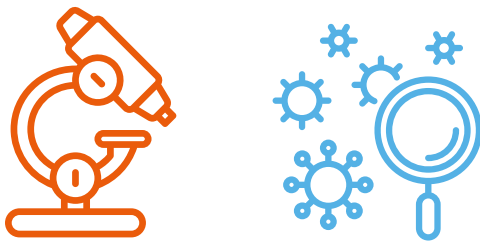




Welcome to the STORM CHASER Study!

Thank you for deciding to take part in this important clinical research study.

This Study Guide will help you understand what you can expect during each of your visits to the study center or mobile unit (if applicable). You may wish to bring it with you to your visits.



If you have any questions, please ask a member of the study team. Contact details can be found on the last page of this Study Guide.



About the STORM CHASER Study

The purpose of the STORM CHASER Study is to research a combination of two investigational monoclonal antibodies for the prevention of COVID-19. COVID-19 is the disease caused by the coronavirus (SARS-CoV-2). The study is looking at how well the investigational monoclonal antibodies work and how safe they are.

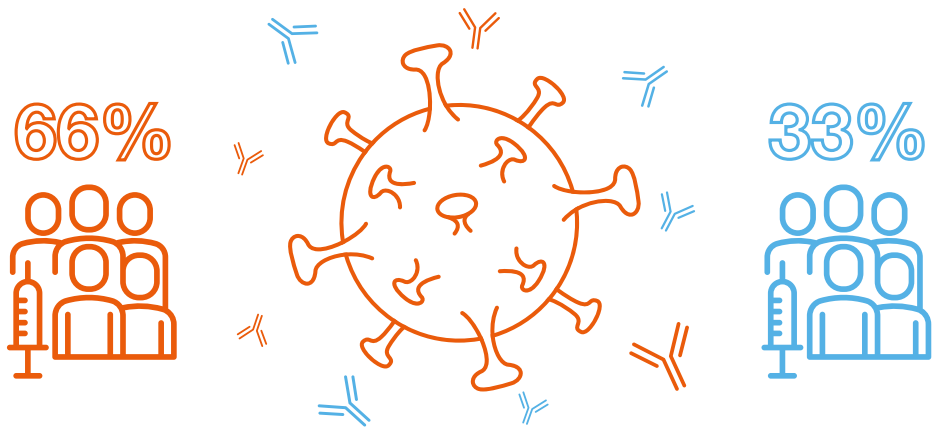
Antibodies are protein molecules that your body produces to help fight infections. Monoclonal antibodies are artificially produced in a laboratory and designed as possible medical treatments.

The investigational monoclonal antibodies are still in the testing and evaluation phase and are not licensed for use in the general public.

Approximately 1125 volunteers will take part in this study.

1125





About the study injections

In this study, you will receive two study injections, at one time, of either the investigational monoclonal antibodies or placebo. The study injections will be given into the muscle of the buttocks.

One in three study participants (33%) will get placebo and two in three participants (66%) will get the investigational antibodies. The placebo looks just like the investigational antibodies but does not contain any active medicine (antibody).

This study is double-blind, meaning that neither you nor the study doctor will know if you are receiving the investigational antibodies. However, if there is a medical emergency, the study doctor will be able to find out.

After receiving the study injections, you may need to stay at the study center for up to 4 hours.

How long will the STORM CHASER Study last?

You will be in the STORM CHASER Study for about 1 year.

Study design



Screening and study treatment visit

(1 day)

You will visit the study center or mobile unit (if applicable) to see if the study is suitable for you and whether you want to take part.

If the study is suitable, you will have some study assessments and receive the two study injections (either the investigational monoclonal antibodies or placebo) at one time.






Follow-up period



(about 1 year)





You will visit the study center or mobile unit (if applicable) six times for study assessments after you have received the study injections. The study team will contact you regularly by phone, email, and/or text. Some participants may also be contacted daily for 4 days after receiving the study injections. Additional visits to the study center, mobile unit (if applicable), and your home may be required if you develop one or more symptoms of COVID-19 during the study.




What tests and assessments will be performed?

The study doctor will perform some health checks at each of your study visits. Some of these checks are described below.

Assessment	Description	Participants	
		All	If you have COVID-19 symptoms
 Physical examination	The study doctor will check the health of your body.	•	•
 Vital signs	Your blood pressure, heart rate, body temperature, and the amount of oxygen in your blood will be measured.	•	•
 Electrocardiogram (ECG)	The study doctor will perform a procedure during which sticky pads are placed on your chest, arms, and legs. The pads are connected by wires to a machine that checks the rhythm and activity of your heart.	•	•

Assessment	Description	Participants	
		All	If you have COVID-19 symptoms
 Pregnancy test (if applicable)	If you are a woman who is able to get pregnant, you will have a urine pregnancy test at each study visit.	•	
 Blood tests	<p>You will need to give some blood, which will be used to check:</p> <ul style="list-style-type: none"> • your general health • if you have SARS-CoV-2 (COVID-19) • if your body has made any antibodies against the investigational antibodies • for any biomarkers (substances in the body) associated with COVID-19 • how well your blood clots • how much of the investigational antibodies are in your body • if your body has naturally produced antibodies against SARS-CoV-2 	• • • • • • •	• • •










Assessment	Description	Participants	
		All	If you have COVID-19 symptoms
 Urine tests	You will be asked to provide urine samples, which will be used to check your health.	●	
 Questions	You will speak to a member of the study team who will ask you questions about your health, any medications you have taken, how you are feeling, and any symptoms and side effects you have.	●	●
 Complete electronic diary (e-Diary)	If you have any symptoms associated with COVID-19, you will need to complete an illness e-Diary about your symptoms for up to 28 days.		●
 Digital health device	You will be given a wearable device that will measure your heart rate, breathing rate, blood oxygen levels, body temperature, and physical activity levels.		●

Assessment	Description	Participants	
		All	If you have COVID-19 symptoms
 Nasal adsorption test	You may have a nose swab taken to test for the presence of the investigational antibodies and any naturally produced antibodies to SARS-CoV-2.	●	●
 Nose and throat swab	A nose and throat swab will be taken to test for COVID-19 and other respiratory infections. You may have more than one swab taken.		●
 Self-collect nose swab	A nose swab will be taken at the study center and self-collected at your home to check for viral shedding of COVID-19.		●

What will happen at my study visits?

This is the schedule of study visits for participants.

The screening and study treatment visit (Visit 1) is not shown in this table.

Procedure		Follow-up visits					
Day		8 (after Visit 1)	29 (about 1 month)	58 (about 2 months)	92 (about 3 months)	183 (about 6 months)	366 (about 1 year)
	Physical examination	•	•	•	•	•	•
	Vital signs	•	•	•	•	•	•
	Blood tests	•	•	•	•	•	•
	ECG						•
	Pregnancy test (if applicable)	•	•	•	•	•	•
	Urine tests	•	•	•	•	•	•
	Nasal adsorption test	•	•		•	•	•
	Questions	•	•	•	•	•	•
	Contact from study team	← Weekly* →					

*Some participants may be contacted daily for 4 days after receiving the study injections and then weekly.

Signs and symptoms of a COVID-19 infection

You or your caregiver should contact the study doctor or study team immediately if you have one or more of the following COVID-19 symptoms of any duration:

- fever
- shortness of breath
- difficulty with breathing
- feeling confused more than usual (if 60 years of age or older)
- loss of appetite or eating less food than usual (if 60 years of age or older)
- increase in the amount of oxygen you are receiving (if 60 years of age or older and already receiving oxygen)



Or if you have one or more of the following symptoms for at least 2 days:


- Chills
- Cough
- Fatigue (tiredness)
- Muscle aches
- Body aches
- Headache
- New loss of taste
- New loss of smell
- Sore throat
- Congestion
- Runny nose
- Nausea (feeling sick)
- Vomiting (being sick)
- Diarrhea



Assessments if you have symptoms of a COVID-19 infection

These are the assessments that will take place if you have symptoms of a COVID-19 infection. If your COVID-19 test is negative, you will be asked to return the digital health device back to the study center and return to your regular study visit schedule.

COVID-19 infection. If your COVID-19 test is negative, and return to your regular study visit schedule.

Day of illness visit schedule	Study center illness visit	Home/self-collection				Study center visit* for participants with a positive COVID-19 test only		
	1	3	5	8	11	14	21	28
 Brief physical exam	•					•	•	•
 Vital signs	•					•	•	•
 ECG								•
 Nose and throat swab	•					•	•	•
 Nasal adsorption test	•					•		•
 Self-collect nose swab	•	•	•	•	•	•	•	•
 Blood tests	•					•		•
 Contact from study team (phone call)		•		•				
 Complete e-Diary	←————— Daily —————→							
 Digital health device	←————— →							
 Questions	←————— →							

*These visits may also take place at your home or mobile unit (if applicable).

What are my responsibilities during the study?

There are some important things to remember while taking part in the STORM CHASER Study.

- Please follow all instructions given to you by the study team at all times.
- If you have symptoms of COVID-19, please contact the study center straight away to inform them and schedule your first illness visit.
- If you have symptoms of COVID-19 and are following the illness visits, please remember to complete your e-Diary and wear your digital health device as instructed by the study doctor.
- Please attend all of your study center visits. These visits are important for your health and safety.
- It is important that you tell the study doctor immediately about any side effects or changes in your health, whether or not you think they are related to the study injections.
- Tell the study doctor about all medications you are currently taking and any changes to these medications.

- Use a highly effective form of birth control during the study.
 - Female participants who are able to get pregnant should use highly effective birth control from Day 1 until 365 days (1 year) after they receive the study injections.
 - Male participants must use a condom from Day 1 until 365 days (1 year) after they receive the study injections.
 - Female participants should not donate ova (eggs) and male participants should not donate sperm for the same period.
- You must not donate blood or plasma for 1 year after receiving the study injections.
- Please tell the study doctor if you no longer wish to participate in the study.





A few things to remember...

- ✓ Taking part in this study is voluntary. You can stop taking part in the study at any time.
- ✓ Please contact a member of the study team as soon as possible if you:
 - are thinking about leaving the study
 - notice any changes in your health
 - cannot attend a study visit and need to reschedule.



Contact information

If you have any questions during the study, please contact the study team.

