Information for Study Participants

We would like to ask if you are interested in participating in a clinical trial concerning an RSV vaccine. This document provides information about the trial and what participation involves. It also explains what is expected of you should you choose to take part, as well as potential risks and benefits associated with the study. Please feel free to discuss the trial with your doctor and ask any questions you may have before deciding whether or not to participate.

What is RSV and what illness does it cause?
Respiratory syncytial virus (RSV) is a common cause of respiratory infections, which are usually mild for most individuals. However, for people in risk groups — such as the elderly, infants, and individuals with underlying medical conditions — RSV can lead to serious complications, such as pneumonia and the need for hospital care. The risk of severe RSV infection increases with age, particularly in individuals over 75 years.

The virus spreads through droplets, meaning infected saliva comes into contact with the mouth, nose, or eyes. RSV can also survive for several hours on surfaces, from which it can be transmitted via the hands. Immunity after RSV infection is short-lived, meaning the illness can reoccur multiple times. Vaccination is an effective way to reduce the risk of severe RSV infection and its potential complications. The Public Health Agency of Sweden recommends RSV vaccination for all individuals over 75 years of age, as well as for those over 60 years with underlying conditions that increase the risk of severe RSV infection, such as lung disease or a weakened immune system.

What is the purpose of the clinical trial?
This trial targets two age groups: adults aged 60–65 and individuals over 80 years.

In 2023 and 2024, three RSV vaccines were approved by the regulatory agencies in Europe and the United States for use in people over 60 years of age. One of these is the Arexvy vaccine, developed by the pharmaceutical company GSK, which will be used in this trial. Arexvy was approved in 2023 and is administered as a single dose into the upper arm muscle. At present, only one dose is recommended, and recent data suggest that protection likely lasts for up to three years after this single dose.

However, there is still limited knowledge about how immune cells respond in people aged 80 and above — the group most in need of protection against RSV infection. The aim of this study is to better understand how the vaccine affects the immune system in older adults, especially those over 80. We will investigate both the effectiveness and duration of the antibody response, as well as the broader immune reaction to the vaccine. We also aim to evaluate whether a booster dose, given one year after the first

dose, can strengthen the immune response and provide longer-lasting protection. The results will help inform better vaccination strategies for these age groups in the future.

Who is responsible for this clinical trial?
The main sponsor and responsible institution for the trial is Karolinska Institutet. The principal investigator and sponsor representative is Professor Karin Loré. Participants are enrolled at the Clinical Trial Unit at the Academic Specialist Centre (ASC), Region Stockholm, and through Familjeläkarna's nursing homes (SÄBO).
This clinical trial has been reviewed and approved by the regulatory authorities in Sweden (the Medical Products Agency and the Swedish Ethical Review Authority).

What does participation in the trial involve?
In total, approximately 65–70 participants will take part in the trial — 30 individuals aged 60–65 years, and 35–40 individuals over 80 years living in nursing homes (SÄBO).

Participation involves attending 10 or 11 study visits over a period of 18 months. All participants will receive two vaccine doses. The first dose will be given at the first visit, and the booster dose will be administered at visit 7, which takes place 12 months after the initial dose.

Participants aged 60–65 will attend visits at the ASC Clinical Trial Unit, located at Sabbatsberg Hospital. Participants over 80 years will be visited in their nursing homes by members of the study team from Familjeläkarna.

During the trial, each participant will have 9 or 10 blood samples taken. Each blood draw will collect between 15 and 40 millilitres of blood (equivalent to 3–8 teaspoons). Blood samples will be taken at the following timepoints:

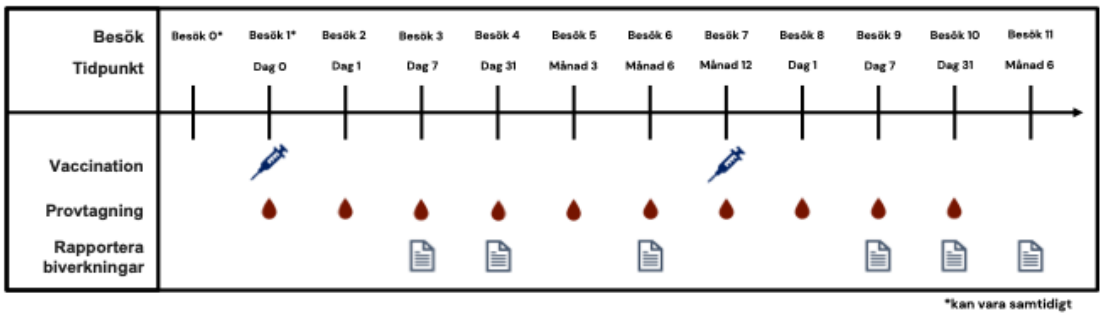
- Day 0 (first visit)
- Day 1 (which may be the same as Day 0)
- Day 7
- Day 31
- Month 3, 6, and 12 after the first dose
- Day 1, Day 7, and Day 31 after the booster dose

These blood samples will be used to study how the immune system — including antibodies, immune cells, and their signalling molecules — responds to the vaccine and how it provides protection against RSV.

Some blood samples will be analysed using RNA and DNA sequencing. RNA (ribonucleic acid) helps the body produce proteins from genes. Our genes are encoded in the form

of DNA (deoxyribonucleic acid) in our cells. Studying the RNA levels and DNA of specific immune cells can increase our understanding of how a vaccine works.

Below is a summary in text and images showing what will take place at each study visit:



Visits 0–1:

At the first visit, you will receive detailed information about the clinical trial and have the opportunity to ask questions. If you decide to participate, you will be asked to provide your written informed consent. We will review your past and current medical history, as well as any medications you are taking. This part of the visit may also be conducted separately, but if not, the visit will continue with a medical examination, including an assessment of your general health, blood pressure, heart rate, and body temperature. Your height and weight will either be measured or taken from your medical records. After that, the vaccine will be administered.

Visits 2–6:

Blood samples will be collected, and you will be asked questions about any symptoms you may have experienced after vaccination and whether you have had any other illnesses (e.g. doctor visits or hospitalisations).

Visit 7:

The booster dose of the vaccine will be administered. The same examinations as at Visit 1 will be performed, including a medical examination. You will also be asked whether you have experienced any symptoms, illnesses, or hospitalisations.

Visits 8–10:

Blood samples will be taken, and you will be asked about symptoms following the vaccine dose and any other illnesses (e.g. doctor visits or hospitalisations).

Visit 11:

This will be a phone call in which you will be asked questions about any symptoms, illnesses, or hospitalisations.

Even though the risk of side effects from the vaccine is considered to be very low, you will receive a diary to record any symptoms during the 4 days following each vaccination. You will keep the diary at home and bring it with you to Visits 2–3 and Visits 7–8. During these visits, the study team will go through the diary with you, and you will then hand it in to the team.

What are the risks of participating in the study?

The Vaccine:

The Arexvy vaccine has been approved in Europe and the United States since 2023. It has been well studied and administered to more than 30,000 individuals in clinical trials. No serious side effects with a confirmed link to the vaccine have been reported.

The most common side effects reported in individuals aged 60 and over are pain at the injection site, fatigue, and muscle, head, or joint pain. Most individuals experienced these symptoms for 1–2 days.

Although no serious side effects linked to the Arexvy vaccine have been reported, there is always a possibility of side effects that are not yet known. All necessary precautions are taken to minimise risk. If you feel unwell or experience any health issues after vaccination, it is important that you inform us as soon as possible.

The Arexvy vaccine used in this study contains a substance called an “adjuvant,” which enhances the immune response to the vaccine. In rare cases (up to 1 in 10,000 individuals), vaccines containing adjuvants have been associated with the development of autoimmune diseases — conditions where the immune system mistakenly attacks the body’s own tissues. These conditions can sometimes be serious and long-lasting. However, autoimmune diseases also occur in individuals who have not received such vaccines. These events are monitored carefully throughout the study.

If you have thrombocytopenia (low platelet levels) or other bleeding disorders, please inform your doctor. The study vaccine, like all intramuscular injections, should be administered with caution in such cases due to the risk of bleeding.

If you have further questions about the risks associated with this vaccine, please speak to the study team, who can explain based on the product label used in your country.

Blood Sampling:

Having blood drawn may cause discomfort, bruising, and in rare cases, a localised inflammation. At each sampling visit, 15–40 ml of blood will be collected (equivalent to approximately 3–8 teaspoons). Over the entire study period, a total of 308 ml of blood will be collected. This can be compared to the 450 ml typically taken when donating blood.

What happens to my personal data?

Data Collection:

Information about you will be collected and recorded during the clinical trial. This includes age, sex, health data (such as current and previous medical conditions), and results from examinations. The collected data will be stored and processed for analysis at Karolinska Institutet.

All personal data will be pseudonymised, meaning they will be coded using a participant number without your name or personal identity number. A code key that links your name and personal number to this participant number will be created and securely stored at the ASC Clinical Trial Unit or Familjeläkarna SÄBO. Access to this key is restricted to authorised personnel only.

The purpose of this data collection is research. Since research is considered to be in the public interest, this serves as the legal basis for processing your personal data. When the study data are analysed, reported, or published, no individual participants will be identifiable.

The data controller for your uncoded personal data is the Stockholm County Healthcare Region (SLSO), and your data will be stored in accordance with SLSO's guidelines for handling personal data. The data controller for your pseudonymised personal data is Karolinska Institutet. These data will be stored on secure servers at Karolinska Institutet and accessed only by authorised study personnel. All data will be handled in accordance with the General Data Protection Regulation (GDPR 2016/679).

Your rights regarding personal data:

According to the GDPR, you have the right to access all data held about you, free of charge, and to have any inaccuracies corrected. You may also request the deletion of your data or restrict how they are used.

- If you are recruited at the Clinical Trial Unit at the Academic Specialist Centre (ASC), Region Stockholm, the Data Protection Officer for your uncoded data is Camilla Heise Löwgren, email: **gdpr.slso@regionstockholm.se**.
- If you are recruited through Familjeläkarna's nursing homes (SÄBO), the Data Protection Officer for your uncoded data is Maiyuan Wester, email: **maiyuan.wester@famlak.se**.
- The Data Protection Officer for your pseudonymised data is reachable at: **dataskyddsombud@ki.se**.

If you are dissatisfied with how your personal data are handled, you have the right to file a complaint with the Swedish Authority for Privacy Protection (Integritetsskyddsmyndigheten). More information is available at: https://www.imy.se

Quality Control and Archiving:

To ensure quality and verify that the trial is conducted properly, an individual appointed by the sponsor or a regulatory authority may compare collected data with your medical records. This quality monitor must sign a confidentiality agreement before accessing your medical records. By signing the informed consent form, you are granting permission for this access if needed. Data collected during the trial will be stored for 25 years after the trial is completed.

What happens to my samples?

The samples collected during this study will be stored in a biobank in coded (pseudonymised) form in accordance with the Swedish Biobank Act (2023:38). This means they cannot be directly linked to you. The code key will be kept securely by the healthcare provider and the responsible investigator, with access restricted to authorised individuals only.

Your samples may be analysed at laboratories within Karolinska Institutet, as well as by collaborating laboratories in Sweden, within the EU/EEA, or outside the EU/EEA, such as in Switzerland. After analysis, your samples may be partially or completely used up. Any remaining material may be stored by the recipient laboratory for up to 15 years.

Your samples may only be used for the purposes to which you have given your consent. If you agree that your samples may be stored for future research, you must provide separate consent. If future research projects not yet planned arise, the Swedish Ethical Review Authority will decide whether you must be re-contacted for additional consent.

You have the right to decline the storage of your samples without giving a reason. If you give consent to store your samples, you also have the right to withdraw that consent at any time. If you do so, your samples will be destroyed. In rare cases, if it is not possible to destroy only your sample without affecting others, your sample will instead be anonymised. If you wish to withdraw your consent, please contact the responsible investigator (see contact details below).

How will I receive information about the results of the trial?

The results from the trial will be registered in a European Union database for clinical drug trials and will be published in scientific journals and presented at national scientific meetings. Only group-level statistics will be reported, and no individual participants will be identifiable.

Information about this clinical trial and others can also be found at:
www.clinicaltrials.gov

You may also ask the principal investigator to inform you of the results once they become available.

Insurance and Compensation

As with any other medical care in Sweden, you are covered by the **Patient Injury Insurance** and the **Pharmaceutical Insurance**.

Participation in the trial will not incur any additional costs for you. You will not receive financial compensation for participating; however, reasonable travel expenses may be reimbursed upon presentation of a receipt.

Participation is Voluntary

Your participation in this clinical trial is entirely voluntary. You may withdraw at any time without providing a reason. Withdrawing will not affect your future care or treatment in any way.

If you wish to discontinue your participation, please contact the responsible person listed below.

Trial Contacts

Sponsor:
Karolinska Institutet
Department of Medicine, Solna
Nobels väg 6
17177 Stockholm

Principal Investigator:
Name: _____
Phone number: _____
Email address: _____

Research Nurse:
Name: _____
Phone number: _____
Email address: _____

Consent to Participate in a Clinical Trial

I have received both verbal and written information about the trial and have had the opportunity to ask questions. I will keep a copy of the written information.

I confirm that:

- I give my consent to participate in the trial titled *"How is the immune system affected by RSV vaccination in older adults? (RISE)"*, and I understand that my participation is entirely voluntary.
- I have received information about how my personal data will be processed and how collected data about me will be stored and handled.
- I give permission for quality monitors appointed by the sponsor or regulatory representatives to access relevant parts of my medical records related to this trial.
- I understand that I may withdraw my consent and end my participation at any time, without providing a reason.

- I give my consent for my samples to be stored in a biobank as described in the participant information sheet.
- I give my consent for my blood samples to be used for genetic analysis as described in the participant information sheet.

I hereby give my consent to participate in the clinical trial.

Participant's Signature **Printed Name** **Date**

_____ _____ _____

Investigator's Signature

I have provided information about the trial, ensured that the participant has understood the information, and that their questions regarding the study have been answered.

Signature **Printed Name** **Date**

_____ _____ _____

A copy of this signed consent form will be provided to the participant.