Participant Information Sheet

Study title: Serine Protease Activity Research in Type 2-low Asthma (SPARTA)

Chief Investigator: Dr Rory Chan, University of Dundee & NHS Tayside
Funder: Asthma + Lung UK

We are inviting you to take part in the research database

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read this sheet carefully, and discuss it with family, friends, or your GP if you wish.

Purpose of the study

Asthma affects many people, but not all types of asthma respond to current treatments. Around 1 in 10 people have a form called type 2-low asthma, which can be difficult to treat.

We believe that a type of white blood cell called a neutrophil may be important in this type of asthma. Neutrophils release proteins, such as neutrophil elastase, which may damage the airways.

This study aims to measure these proteins in people with asthma to see whether type 2-low asthma is linked with higher neutrophil activity. This could help identify new treatment options in the future.

With your consent, what is being tested?

We are studying whether a type of white blood cell called a neutrophil plays an important role in a difficult-to-treat type of asthma known as type 2-low asthma. Neutrophils release proteins, such as neutrophil elastase, which may damage the lungs. We will test sputum (phlegm) and sometimes blood samples to measure these proteins.

Why have I been contacted?

You have asthma and receive care in NHS Tayside. You may be eligible to take part because we are recruiting adults with moderate-to-severe asthma.

Do I have to take part?

No. Taking part is voluntary. If you choose not to, or decide to withdraw later, your usual care will not be affected.

What will happen to me if I take part?

You will attend your routine clinic appointment lasting about 1 hour. At this visit you will:

- Provide a sputum sample. If you are unable to produce sputum, we will give you a nebuliser with saline (salty water) to help you.

- Do breathing tests.
- Complete questionnaires about your asthma.
- Provide a small blood sample.

Consent Process

You will receive this information sheet and have time to decide. A member of the research team will answer your questions. If you choose to take part, you will be asked to sign a consent form.

Screening and Eligibility

Your doctor will first check your records to confirm you meet the eligibility criteria (e.g. diagnosis of asthma, age 18+).

Number and Location of Visits

One visit at Ninewells Hospital, Dundee.

Duration of Participation

Your involvement will end after this single visit.

Involvement of Your GP

With your consent, your GP will be informed that you are taking part.

Tissue Samples

Sputum and blood samples will be analysed for neutrophil proteins. Samples may be kept securely for future ethically approved research, if you consent. Otherwise, they will be destroyed after the study.

Research Data

Your data will be coded with a study ID. Researchers analysing results will not know your identity.

Expenses and Payments

As you will be attending for your routine clinic appoint, no payment will be made.

Genetic Research

This study will not involve DNA testing or genetic research.

Exposure to Radiation

No radiation is involved.

What if New Information Becomes Available?

If new findings arise during the study that could affect your decision to participate, we will inform you immediately.

Withdrawal from the Study

You can withdraw at any time without giving a reason. Data and samples already collected may still be used in anonymised form unless you request otherwise.

Loss of Capacity

If a participant loses the ability to consent during the visit (very unlikely), they will be withdrawn immediately. No further data or samples will be collected.

What Happens at the End of the Study?

Once the last participant has completed their visit and all analyses are finished, the study will end.

Will I Find Out the Results?

Yes. We will prepare a plain-language summary and can send it to you if you wish. Results will also be shared on the University of Dundee and Asthma + Lung UK websites.

What if I Become Pregnant During the Study?

This study involves no treatments or medicines. If you become pregnant, you may still take part, unless you prefer not to provide samples.

Will taking part in the study affect my usual care?

No. Your normal NHS asthma care will continue as usual.

What are the possible benefits of taking part?

You may not benefit directly, but your participation may help improve understanding of asthma and lead to better treatments in the future.

What are the possible disadvantages and risks of taking part?

Medical Risks

- Sputum collection may cause coughing.
- Breathing tests may cause temporary breathlessness or dizziness.
- Blood tests may cause slight pain, bruising, or (rarely) fainting.

Psychological Risks

Answering questionnaires may feel repetitive but should not cause distress.

Confidentiality Risks

There is a small risk of data breach, but strong safeguards are in place to keep your data secure.

Incidental Findings

The laboratory tests are research only and not designed to provide clinical results. It is unlikely that results of individual clinical significance will arise.

Who is organising and funding this research?

This study is led by Dr Rory Chan at the University of Dundee and NHS Tayside. It is funded by Asthma + Lung UK.

What if something goes wrong?

If you are concerned about your participation in the study you have the right to discuss your concern with a researcher involved in the study or a doctor involved in your care. If you have a complaint about your participation first of all please talk to the researcher. If you are not satisfied, you can make a formal complaint to a senior member of the research team or to the Complaints Officer for NHS Tayside.

[Patient Experience Team
NHS Tayside
Ninewells Hospital
Dundee DD1 9SY
Freephone: 0800 027 5507
Email: TAY.feedback@nhs.scot]

If you think you have come to harm due to taking part in the study there are no automatic arrangements to get financial compensation.

Who has reviewed this study?

This study has been reviewed and approved by East of Scotland Research Ethics Committee, an independent group responsible for reviewing research involving people to ensure it is ethical and safe. The REC has raised no objections to the study going ahead.

Contact details for further information.

For any questions or additional information about the study, please contact the research team at the site:

Dr Rory Chan

Consultant Respiratory Physician

rory.chan@nhs.scot

If you would like independent, unbiased advice, you may also contact an external advisor:

Dr Richard Hammond

Consultant Respiratory Physician

richard.hammond5@nhs.scot

Thank you for taking the time to read this information and considering participation in this study.

APPENDIX

How will we use information about you?

We will need to use information from you, your medical records and your GP for this research project.

This information will include:

- Your name
- Your contact details
- Your CHI number
- Your date of birth
- Clinical data such as test results, questionnaires and hospital visits

The research team that includes clinicians will use this information to carry out the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead (pseudonymisation).

The University of Dundee is the sponsor of this research and is responsible for looking after your information. We will keep all information about you safe and secure by:

- Storing data in secure, password-protected databases (e.g. REDCap) on University of Dundee servers
- Limiting access to only approved study team members
- Encrypting data during transfer using secure file transfer protocols
- Auditing all data access and transfers regularly
- Ensuring compliance with the Data Protection Act 2018 and UK GDPR

International transfers

We may share data about you outside the UK for research-related purposes to:

- Collaborate with approved international research partners
- Allow statistical analysis or software development in countries outside the UK

If this happens, we will only share the minimum data necessary and, where possible, in a form where you cannot be identified. However, in rare cases such as very specific conditions, re-identification may still be theoretically possible.

Data shared outside the UK will only go to the following types of organisations:

- Academic research collaborators
- Contracted secure data processors (e.g. for secure cloud storage or data analysis)

We will ensure your data is protected by:

- Using countries with an "adequacy decision" from the UK government, or
- Using standard contractual clauses approved for international data transfer
- Requiring recipients to use equivalent security and confidentiality measures
- Prohibiting further sharing or unauthorised uses of your data

- Having procedures in place for managing any data breaches

How long will we keep your data?

Once the study has ended, we will keep your data so we can check the results. We will write all reports in a way that means no one can identify you. We will keep your study data for a maximum of 10 years. After this, the data will be either fully anonymised and archived or securely deleted, depending on future research value and legal obligations.

What are your choices about how your information is used?

You can stop being part of the study at any time without giving a reason. We will keep the data collected up until that point. If you choose to stop taking part, we would like to continue collecting information about your health from your GP or hospital. If you do not want this to happen, please tell us and we will stop. You have the right to ask us to remove or correct your data. However, we might not be able to do this if it would affect the research. If that's the case, we will explain why. You may be asked whether you consent to your data being used in future related research. This is optional.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

By speaking to a member of the research team

By emailing: rory.chan@nhs.scot

Or at: www.hra.nhs.uk/patientdataandresearch

If you wish to contact the sponsor's Data Protection Officer, please contact:

[Umran Sarwar, u.z.sarwar@dundee.ac.uk]

GDPR Statement

This study will be conducted in accordance with the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018. Your personal data will be collected, stored, and used only for the purposes of this research. Identifiable information will be kept secure and access will be strictly limited to authorised members of the research team. Where possible, data will be pseudonymised or anonymised. You have the right to access, correct, or request deletion of your personal data, although in some cases it may not be possible to delete data already used in analyses. Further details can be obtained from the study team or the University of Dundee's Data Protection Officer (u.z.sarwar@dundee.ac.uk).