Informed Consent

Title of Research: Effects on the Olfactory Epithelium and the Olfactory Nerve from Exposure to Diesel Exhaust

Lung and Allergy Section, Norrland University Hospital
Umeå, Sweden

Principal Investigator: Dr. Ala Muala
Co-Investigators: Prof. Thomas Sandström, Prof. Anders Blomberg

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Background

Exposure to air pollution, such as particles from traffic and biomass combustion, affects various organ systems. Recent studies have highlighted wood smoke and diesel exhaust as risk factors for dementia and cognitive impairment due to long-term exposure. Some studies from Sweden and abroad indicate that wood smoke may irritate mucous membranes and affect lung and cardiovascular disease, while certain types of particles may reach the brain directly via the sense of smell. It is valuable to study the mechanisms behind these health effects, as authorities in our country encourage small-scale wood burning as an alternative heat source, making research into the symptoms and health impacts of wood smoke important.

All combustion processes can theoretically generate particles that may be carcinogenic. Wood-burning particles are considered to pose very little such risk—much less than particles from diesel and gasoline engines. Even experimental exposures to these particles are associated with extremely low risk, as occupational and population studies have shown only very weak links between cancer and many decades of heavy exposure to old diesel exhaust.

Purpose and Expected Benefits of the Project

This study aims to examine whether diesel exposure affects the olfactory nerve. The mechanism behind dementia development due to air pollution is not established. This study seeks to investigate the first barrier mechanism protecting the brain by looking at how these particles affect the olfactory nerve.

Project Design

As a study participant, you will undergo an initial medical examination and then be exposed once to diluted diesel exhaust. The exposure will last 1 hour, alternating light exercise on a test bike with rest in 15-minute intervals. Blood samples will be taken before and after exposure to analyze inflammation.

Immediately after exposure, a small (2 mm) sample of nasal mucosa will be taken under local anesthesia.

Data Handling and Confidentiality

Samples collected during the study will be coded, and those not analyzed immediately will be frozen for later analysis within this project. The responsible researcher will only have access to information about the type of exposure, which is important for the design of the analyses. Samples will not be used for any purpose outside this research project. All data and results will be handled according to confidentiality rules, and published data will never allow identification of individual participants.

Your samples will be stored in a biobank at Västerbotten County Council (VLL) for future studies performed at the Lung and Allergy Research Laboratory. If additional studies outside the scope of this project are planned, they will be reviewed by a regional ethics board, which will determine whether you need to be asked for consent again.

As noted, all samples are coded, and the code key allowing identification is securely stored at the Lung and Allergy Section of Norrland University Hospital. The person responsible for the samples is Dr. Ala Muala, consultant physician, Lung and Allergy Section, Norrland University Hospital, 90185 Umeå. You have the right to refuse storage of your samples or later withdraw your consent, and you may request that your samples be destroyed at any time.

The project will collect and record personal information, medical examination results, and blood/tissue sample results in a research journal stored securely at the Medical Center. Research data will be stored on secure computers, all coded, for at least 10 years. The responsible researcher will be the only person with access to the code key. All published results will be presented at a group level only. Your information and samples will not be transferred outside the EU or EEA.

Your records and results will be protected against unauthorized access. VLL is responsible for your personal data. Under the EU General Data Protection Regulation, you have the right to access your data free of charge, request corrections, request deletion, or limit processing of your personal data. You can contact the responsible researcher (see below) or VLL's Data Protection Officer Dan Harnesk (dataskyddsombud@vll.se). If dissatisfied with how your data is handled, you may file a complaint with the Swedish Data Protection Authority.

Potential Risks to Participants

The study involves an extra biopsy from healthy tissue. The risk is minimal, with virtually no risk of bleeding or pain.

Insurance

Participation is entirely voluntary, and you may withdraw at any time without affecting your relationship with the Lung and Allergy Section or the investigators.

Participants completing the study will receive SEK 3000 compensation.

You are insured as a research participant through the Patient Insurance scheme.

Voluntary Participation

Participation is voluntary and can be discontinued at any time without explanation. Refusal or withdrawal will not affect your future medical care. If samples have been taken, you may request that they be destroyed or rendered untraceable to you.

Project Contacts

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Consent Form

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Principal Investigator: Dr. Ala Muala

Co-Investigators: Prof. Thomas Sandström, Prof. Anders Blomberg

Institutional Contact: Lung and Allergy Department, Norrland University Hospital

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Sweden
Phone: 090-7851867

I have received oral information about the study and have read the written information above. I consent to participate in the study, understanding that participation is completely voluntary and can be withdrawn at any time without explanation or impact on future care. I consent to the processing of my personal data and to storage of my samples in a biobank.

Date: ..... Participant's signature: .....

Participant's name: .....

I have explained the study's design and purpose to the above research participant:

Date: ..... Physician's signature: .....

Physician's name: .....