Plan Overview

A Data Management Plan created using DeiC DMP

Title: AIRCARD

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Template: DCC Template

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Project abstract:

Background: The AIRCARD study is designed to investigate the relationship between long-term exposure to air and noise pollution and cardiovascular disease incidence and mortality.

Aim: To conduct a robust prospective cohort analysis assessing the cumulative and differential impacts of air and noise pollution exposure on cardiovascular disease and mortality. This study will adjust for relevant confounders, including traditional cardiovascular risk factors, socioeconomic indicators, and medication use.

Methods: This prospective cohort study will include 27,022 male participants aged 65-74, recruited from the two large Danish DANCAVAS and VIVA trials, both population-based randomized, multicentered, clinically controlled studies. We will assess long-term exposure to air pollutants using the state-of-the-art DEHM/UBM/AirGIS modelling system and noise pollution through the Nord2000 and SoundPLAN models, covering data from 1979 to 2019. This statistical analysis plan is strictly formulated to predefine the analytical approach for all outcomes and key AIRCARD study variables before data access. The primary analysis will utilize Cox proportional hazards models, adjusted for confounders identified in our cohort (age, body mass index, hypertension, diabetes, smoking status, family history of heart disease, socioeconomic factors, and medication use). This statistical analysis plan further includes Spearman rank correlation to explore inter-pollutant associations.

Discussion: The AIRCARD study addresses global concerns about the impact of air and noise pollution on cardiovascular disease. This research is crucial for understanding how the pollutants contribute to cardiovascular disease. We aim to provide valuable insights into this area, emphasizing the need for public health measures to mitigate pollution exposure. Our goal is to provide policymakers and healthcare professionals with information on the role of environmental factors in cardiovascular health that could influence global strategies to reduce the cardiovascular disease burden associated with pollution. The design of this statistical analysis plan ensures transparency and verifiability, considering the complexities of evaluating environmental health impacts over an extended period.

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AIRCARD

Data Collection

What data will you collect or create?

Project Description
The AIRCARD study is a prospective cohort analysis investigating the long-term effects of air and noise pollution on cardiovascular disease (CVD) incidence and mortality. It addresses research questions on the relationship between environmental pollution exposure and CVD in a large population. This study is conducted in Denmark, utilizing data from the DANCAVAS and VIVA trials, covering male participants aged 65-74. The study is guided by ethical standards and data collection protocols, with a particular focus on detailed environmental exposure modeling using advanced tools like DEHM/UBM/AirGIS and Nord2000/SoundPLAN.

Related Policies
The AIRCARD study adheres to data management, sharing, and security policies. These include guidelines from the Danish Data Protection Agency, ethical standards from the health research ethics committees, and data management protocols from the participating institutions. The study complies with the General Data Protection Regulation (GDPR) for data handling and privacy.

Regarding permissions, the study has ethical approval from the Danish National Committee on Health Research Ethics.

What data will you collect or create?
The AIRCARD study will handle data types including environmental pollution data, health outcome data, and demographic information. The data format is quantitative, collected from databases like the DANCAVAS and VIVA trials. This includes detailed pollution exposure assessments using DEHM/UBM/AirGIS and Nord2000/SoundPLAN models. Existing data from these trials are being reused, ensuring a comprehensive analysis of the long-term effects of air and noise pollution on cardiovascular health.

How will the data be collected or created?

From the DANCAVAS and VIVA trials and Danish Registries.

Documentation and Metadata

What documentation and metadata will accompany the data?

For the AIRCARD study, we're ensuring that the data is accompanied by documentation and metadata. This includes descriptions of how we collect and analyze data, plus a codebook that explains all the variables and their meanings. We're also creating a flowchart to show the steps from participant recruitment to data analysis. This approach makes sure that anyone in the future can understand and use our data properly. We're focusing on consistency and quality.
Data control will ensure high data quality. We will set specific requirements for categorical variables and check their values for consistency. For numerical variables, we'll define acceptable ranges and verify data within these intervals. Dates and times will be checked for proper

Ethics and Legal Compliance

How will you manage any ethical issues?

For ethical issues, the AIRCARD study ensures participant consent for data preservation and sharing, focusing on protecting identities through pseudonymization. Sensitive data is handled securely, adhering to strict protocols for storage and transfer.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

Regarding copyright and Intellectual Property Rights, the ownership of data will align with institutional and funding body policies.

Storage and Backup

How will the data be stored and backed up during the research?

On the Danish Statistics (DST) server and at Open Patient data Explorative Network (OPEN).

How will you manage access and security?

DST and OPEN manages this.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

The cohort, the pollution exposure, and the outcome events will all be retained, preserved, and shared under certain circumstances described below.

What is the long-term preservation plan for the dataset?

At the above-mentioned servers.

Data Sharing

How will you share the data?

We will share data with researchers who provide a methodologically sound proposal and who undergo certifications and acceptance by relevant review committee (by ENVS, OPEN and Statistics Denmark).

Are any restrictions on data sharing required?

Question	Authors' Response
Will the data collected for your study be made available to others?	Yes.
Which data? Additional information about data	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).
When will data availability begin?	Beginning 3 months following article publication.
When will data availability end?	Ending 5 years following article publication.
Will any supporting documents be available?	Yes.
Which supporting documents?	Study Protocol, Statistical Analysis Plan.
Additional information about supporting documents	None.
How or where can supporting documents be obtained?	They are published at …
When will supporting documents availability begin?	They are available at all times.
When will supporting documents availability end?	They will not end.
To whom will data be available?	Researchers who provide a methodologically sound proposal and who undergo certifications and acceptance by relevant review committee (by ENVS, OPEN and Statistics Denmark).
For what type of analysis or purpose?	To achieve aims in the approved proposal.
By what mechanism?	Proposals should be directed to Stephan.mayntz@gmail.com.
Any other restrictions?	None.
Additional information	None.

Responsibilities and Resources

Who will be responsible for data management?

Our primary investigator will be responsible for all data management.

What resources will you require to deliver your plan?

We will collaborate with OPEN to deliver the plan.