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Investigating the relationship between aortic aneurysms and air pollution using excess aortic samples from surgery and organ donors

Submission date 28/03/2023	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 31/03/2023	**Overall study status** Ongoing	
Last Edited 07/11/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims

An aneurysm occurs when the wall of a blood vessel weakens and balloons out. This can occur in many of the arteries of the body including the aorta. The ballooning of the aorta makes the wall much weaker and more likely to rupture, this most commonly occurs in the section of the aorta that passes through the abdomen. These are known as abdominal aortic aneurysms (AAA). Ruptures are catastrophic events where 4 out of 5 people with a rupture will die. There is currently no treatment for AAAs that can prevent them from developing or expanding in size, they can however be offered major surgery when the aneurysm reaches a certain size. The exact cause for AAAs and factors that lead to the expansion and rupture of AAAs are not known, although several risk factors are known. Air pollution is implicated in the development and severity of numerous diseases, including cardiovascular diseases (CVD), which account for more than half of the deaths attributed to air pollution. The main aim of this study is to understand the relationship between air pollution and aortic aneurysms. The study will involve the collection of samples of the aortic wall. During open surgical repair of the aorta, the aneurysm is cut open and the wall of the aneurysm is usually trimmed off and closed over a fabric graft. When a kidney transplant occurs the donated kidney normally contains a section of the aorta that the surgeon can use to fashion a new joint. Often excess 'healthy' aorta is trimmed off here as well and discarded. The researchers hope to keep these two excess sections of the aorta that are normally disposed of and compare them in the lab, looking for evidence of air pollutants.

Who can participate?

Patients undergoing a surgical repair of their aorta

What does the study involve?

This study will not change the medical care that participants would normally receive. Participants will come to the hospital for their routine appointments and undergo surgical repair of their aortic aneurysm just as planned by their doctors. The researchers would like to keep a sample of the aneurysm wall that is normally trimmed off during surgery and a sample of blood taken before surgery alongside routine blood tests (an additional two small tubes). These samples (aortic tissue and blood) will be kept and stored and used to research aortic aneurysms,

in this case to look for the presence of air pollutants. The researchers would also like participants to answer a short questionnaire on environmental and occupational exposures that should only take 10 or 15 minutes to complete. This will include questions about employment and cities lived near, to understand their true lifetime exposure to air pollutants.

What are the possible benefits and risks of participating?
If the study is successful, it will hopefully increase knowledge of the effect of air pollution on health and aortic aneurysms. Taking part in the study will be of no direct benefit to the participant.

Where is the study run from?
University of Leicester (UK)

When is the study starting and how long is it expected to run for?
September 2022 to July 2028

Who is funding the study?
University of Leicester (UK)

Who is the main contact?
Liam Musto, lm503@leicester.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
309106

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 309106, CPMS 55152

Study information

Scientific Title
InvestigAtion into the relAtionship between AortiC aneurysmaL disease and air pOllUtion using Intraoperative samples from live donors and cadaveric organ Donors (AAA-CLOUD)

Acronym
AAA-CLOUD

Study objectives
This study aims to collect human vascular tissue samples from renal transplant organ donors and from live donors undergoing elective/emergency open surgical repair of aortic aneurysms to determine the role of air pollutants and environmental exposure in the formation of aortic aneurysms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/03/2023, East Midlands - Leicester Central Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)2071048066, +44 (0)2071048199; leicestercentral.rec@hra.nhs.uk), ref: 23/EM/0019

Study design
Observational case-control study

Primary study design
Observational

Study type(s)

Other

Health condition(s) or problem(s) studied
Abdominal aortic aneurysm

Interventions
Many of the organs that become available for transplant are from patients relatively free of pre-existing vascular disease, the cause of death in such cases is usually traumatic or neurological and often of sudden onset. This study will only obtain specimens from those organ donors where consent has been given for use of surplus tissue. Samples from live donors donating excess tissue during open surgical procedures of the aorta will be consented prior to intervention. During open surgical repair of aortic aneurysms, the aneurysm sac is opened and depending on the type of repair usually a synthetic graft is sewed in place to exclude the aneurysm. This leaves a redundant aortic aneurysm sac which is usually trimmed and sewed closed over the graft to protect it depending on surgeon preference. Viable trimmed aneurysm wall which would otherwise be clinical waste will be retained and used for the study analysis. The excess vascular tissue will be divided into three sections at the point of collection in the operating theatre. These sections will be used as control/study tissue with three different types of processing.

Intervention Type
Other

Primary outcome(s)
Level of magnetite in micrograms per gram of dry tissue measured using magnetic analyses at the time of sampling compared between aneurysm tissue and controls

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
01/05/2028

Eligibility

Key inclusion criteria
Undergoing open aneurysm repair or cadaveric kidney donor (death due to non vascular causes)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. No valid consent
2. Patients undergoing emergency surgery or in extremis

Date of first enrolment
01/07/2023

Date of final enrolment
01/07/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Glenfield General Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
University/education

Funder Name
University of Leicester

Alternative Name(s)
UniofLeicester, UoL

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes