

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/03/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/09/2023	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

309106

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Case-control study

Study setting(s)

Hospital, Medical and other records

Study type(s)

Other

Participant information sheet

Not available in web format at present please use contact details if you would like to request a participant information sheet

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 measure

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

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/09/2022

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)

Mixed

Age group

Adult

Sex

Both

Target number of participants

100

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**

England

United Kingdom

Study participating centre

Glenfield General Hospital

Grobby Road

Leicester

United Kingdom

LE3 9QP

Sponsor information**Organisation**

University of Leicester

Sponsor details

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Research Ethics, Governance & Integrity Office

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Sponsor type

University/education

Website

<http://www.le.ac.uk/>

ROR

<https://ror.org/04h699437>

Funder(s)

Funder type

University/education

Funder Name

University of Leicester

Alternative Name(s)

UoL

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Publication in a high-impact peer-reviewed journal

Intention to publish date

01/05/2029

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