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Evaluating an artificial intelligence tool for measuring the aorta from computed tomography (CT) scans

Submission date 02/05/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 06/05/2026	**Overall study status** Ongoing	
Last Edited 05/05/2026	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
The aorta is the body's main blood vessel, carrying blood from the heart to the rest of the body. It can become enlarged over time, which may lead to serious and life-threatening conditions. Doctors use CT scans to measure the size of the aorta and monitor patients. A CT scan is a test that takes detailed pictures of the inside of your body. Currently these measurements are made by hand by specialist doctors, which takes time and can vary between readers. Aorta AIM is an AI software tool designed to make these measurements automatically. This study aims to test how accurately Aorta AIM measures the aorta from CT scans compared to specialist doctors.

Who can participate?
The study will use CT scan images obtained as part of routine clinical care at three NHS hospitals in England. All patient-identifying information is removed before the data is used for research. No patients are directly approached or recruited. Data may be included unless the patient opted out of NHS data sharing through the National Data Opt-Out programme.

What does the study involve?
Existing CT scans from routine clinical care are identified by staff at each hospital and stripped of any patient-identifying information. Aorta AIM measures the aorta from each scan. Specialist doctors then measure the same scans, without seeing the AI results or each other's measurements. The two sets of measurements are then compared to assess how accurately Aorta AIM performs. No patients are contacted and no changes are made to anyone's care.

What are the possible benefits and risks of participating?
There are no risks to patients as this study only uses existing scan images with no patient contact. All patient-identifying information has been removed from the data. If Aorta AIM performs well, it could in future help doctors measure the aorta more quickly and consistently, benefiting patients with aortic conditions.

Where is the study run from?
The study is led by Northumbria Healthcare NHS Foundation Trust, with research activities also

taking place at Newcastle upon Tyne Hospitals NHS Foundation Trust and South Tyneside and Sunderland NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
May 2026 to September 2026.

Who is funding the study?
AIATELLA Oy (Finland).

Who is the main contact?
Jack Parker - research@aiatella.com, jack@aiatella.com

Contact information

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Scientific, Public

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Integrated Research Application System (IRAS)
356296

Central Portfolio Management System (CPMS)
71579

Study information

Scientific Title
AI-CARE: Artificial Intelligence for Cardiovascular Analysis and Risk Evaluation

Acronym
AI-CARE

Study objectives

Ethics approval required
Ethics approval not required

Ethics approval(s)

Primary study design
Observational

Secondary study design
Retrospective validation study

Study type(s)

Health condition(s) or problem(s) studied
Aortic pathology, including aneurysm and dissection

Interventions
Retrospective CT studies from adult patients who underwent routine clinical aortic imaging at three NHS Trusts in England between January 2016 and August 2025 are identified and pseudonymised by the local clinical care team at each site. Pseudonymised DICOM images and demographic data (age, sex) are transferred to a secure research environment. The Aorta AIM v1. 0 software processes each scan to produce automated measurements of maximum aortic diameter across standardised anatomical regions. Separately, fellowship-trained radiologists and /or cardiologists independently measure the same scans following a standardised measurement protocol, remaining blinded to AI outputs and to each other's measurements throughout. An independent statistician then compares AI and expert measurements. No patient contact occurs at any stage.

Intervention Type
Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Aorta AIM v1.0

Primary outcome(s)
1. Mean Absolute Error (MAE) between Aorta AIM v1.0 automated measurements and expert consensus reference measurements measured using absolute difference in mm, with 95% confidence interval at time of analysis

Key secondary outcome(s))
1. Agreement between Aorta AIM v1.0 and expert consensus maximum aortic diameter measurements measured using Intraclass Correlation Coefficient (ICC) at time of analysis

2. Systematic bias and variability between Aorta AIM v1.0 and expert consensus measurements measured using Bland-Altman limits of agreement in mm, reported descriptively at time of analysis

3. Technical processing success rate of Aorta AIM v1.0 measured using percentage of successfully processed scans at time of AI processing

4. Clinical acceptability of Aorta AIM v1.0 measurements as assessed by expert readers measured using a visual scoring scale, summarised by distribution across scores and regions at time of expert review

Completion date
28/08/2026

Eligibility

Key inclusion criteria
1. Adults ≥22 years at time of imaging
2. Imaging performed 1 Jan 2016 – 31 Aug 2025
3. CT imaging of the whole, thoracic, or abdominal aorta, with or without contrast enhancement
4. Slice thickness ≤3mm

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
22 years

Upper age limit
120 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Metal implants <5cm from aorta (e.g. thoracic stent)
2. Prior aortic surgery
3. Severe motion artifacts (e.g. >3mm vessel blurring)
4. Congenital aortic anomalies (e.g. coarctation, vascular rings)
5. Post-traumatic aortic repairs
6. Patient opted-out of having their data used for medical research via the NHS 'National patient opt-out scheme' before
the date of cross-referencing by the site team

Date of first enrolment
11/05/2026

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Northumbria Healthcare NHS Foundation Trust
North Tyneside General Hospital
Rake Lane
North Shields
England
NE29 8NH

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
England
NE7 7DN

Study participating centre

South Tyneside and Sunderland NHS Foundation Trust
Sunderland Royal Hospital
Kayll Road
Sunderland
England
SR4 7TP

Sponsor information

Organisation
AIATELLA Oy

Funder(s)

Funder type

Funder Name
AIATELLA Oy

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available