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Aneurysm WAtch coRonary artEry study

Submission date 31/12/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/02/2025	**Overall study status** Ongoing	
Last Edited 04/02/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Coronary artery ectasias and aneurysms (CAEA) are when parts of the coronary arteries are abnormally widened. These are found in 2-7% of patients who undergo tests for heart issues. Evidence suggests that up to 10% of patients with CAEA may experience serious heart problems each year, with heart attacks often being the first sign of CAEA. About 5% of heart attack patients have aneurysms (a bulge in the blood vessel wall) in the affected artery. We don't know much about the long-term outcomes for CAEA, and no detailed studies have been done yet. This study aims to find out whether patients with CAEA have worse long-term outcomes (measured by overall death rates) compared to similar patients without CAEA.

Who can participate?
Patients aged 18 years or older with CAEA diagnosed via coronary angiography (cases) and matched patients without CAEA

What does the study involve?
This is an observational, non-interventional study. Follow-up data of participants, including mortality and major adverse cardiovascular events (MACE), is obtained via clinical visits, telephone contact with the patients' families, and the National Registry of Births and Deaths.

What are the possible benefits and risks of participating?
Participation in the study does not bring any additional risk to the patients or controls. Participants face no direct medical benefit as the study does not alter their care. However, participation in the study offers the benefit of contributing to scientific knowledge and improved healthcare practices.

Where is the study run from?
The study will be conducted at St. John Paul II Hospital, Krakow, Poland

When is the study starting and how long is it expected to run for?
June 2007 to December 2028

Who is funding the study?
1. Jagiellonian University Medical College, Krakow, Poland
2. National Science Centre, Krakow, Poland
3. St John Paul II Hospital, Krakow, Poland

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

U1C/W41/NO/28.26

Study information

Scientific Title
Aneurysm WAtch coRonary artEry study (AWARE-ANEURYSM): matched-pair clinical follow-up analysis from a prospective database of 10,918 patients undergoing coronary angiography

Acronym
AWARE-ANEURYSM

Study objectives
The study tests the hypothesis that clinical course (with all-cause mortality as primary endpoint) may be worse in patients with aneurysmal coronary artery disease (in presence or absence of atherosclerotic coronary disease) than in clinically and angiographically matched patients without aneurysmal coronary artery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/03/2018, Jagiellonian University Bioethics Committee (Skawinska 8, Krakow, 31-066, Poland; +4812 4332743; komisja_bioetyczna@cm-uj.krakow.pl), ref: 1072.6120.64.2018

Study design
Single-centre 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
No participant information sheet available

Health condition(s) or problem(s) studied
Aneurysmal coronary artery disease, Coronary artery aneurysm, Coronary artery ectasia

Interventions
AWARE-ANEURYSM is a study of coronary artery ectasias and aneurysms (CAEA) natural history modified by procedures performed as per medical requirements (guideline-based medical standards). There are no protocol differences in management between study groups. Patients receive their usual care. Follow-up data of participants, including mortality and major adverse

cardiovascular events (MACE), is obtained via clinical visits, telephone contact with the patients' families, as well as via national and local databases.

Study group
Participant inclusion criteria:

Control group

Intervention Type
Other

Primary outcome measure
All-cause mortality verified through the databases of the National Registry of Births and Deaths (Central Statistical Office, Warsaw, Poland) and St. John Paul II Hospital, Kraków, Poland, in Q4 2028

Secondary outcome measures
Major adverse cardiovascular events (death, nonfatal myocardial infarction, nonfatal stroke), data recorded in the databases of St. John Paul II Hospital, Kraków, Poland, and/or obtained via clinical visits or telephone contact with the patients' families in Q4 2028

Overall study start date
04/06/2007

Completion date
31/12/2028

Eligibility

Key inclusion criteria
Cases:
1. All-comer patients with CAEA (defined as the presence of coronary artery dilation that exceeds the adjacent segment diameter by at least 50%) diagnosed via coronary artery angiography.
2. Age over 18 years

Controls:
(CAG and clinical-matched) participants without aneurysmal coronary artery disease. Best-match patients based on: gender, age, type 2 diabetes, history of myocardial infarction, left ventricular impairment, presence and location of coronary artery stenoses, and history of coronary revascularization (percutaneous coronary intervention or coronary artery bypass grafting).

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
at least 500 (250 cases + 250 controls)

Total final enrolment
506

Key exclusion criteria
Not meeting the participant inclusion criteria

Date of first enrolment
04/01/2008

Date of final enrolment
27/12/2017

Locations

Countries of recruitment
Poland

Study participating centre
Department for Cardiac and Vascular Diseases, Jagiellonian University Medical College, St. John Paul II Hospital
Pradnicka 80
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Sponsor information

Organisation
Jagiellonian University

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University Medical College, sw. Anny 12
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+48126631100
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Sponsor type

Research organisation

Website
https://www.uj.edu.pl

ROR
https://ror.org/03bqmcz70

Organisation
National Science Centre Poland

Sponsor details
Twardowskiego 16
Krakow
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30-312
+48123419003
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Sponsor type
Research organisation

Website
https://ncn.gov.pl/

Organisation
John Paul II Hospital

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sekr_kard@szpitaljp2.krakow.pl

Sponsor type
Hospital/treatment centre

Website
http://www.szpitaljp2.krakow.pl/Hospital.34+M52087573ab0.0.html

ROR
https://ror.org/01apd5369

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Uniwersytet Jagielloński Collegium Medicum

Alternative Name(s)
Jagiellonian University Medical College

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Poland

Funder Name
John Paul II Hospital Research Fund

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2029

Individual participant data (IPD) sharing plan
According to the National Science Centre (Poland) data sharing policy data sharing is obligatory and the final database will be made available upon completion of the project.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request